

EPA Jacket 88052-8



U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Registration Division (7505C)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

EPA Reg. Number:

88052-8

Date of Issuance:

DEC 13 2012

NOTICE OF PESTICIDE:

☒ Registration
☐ Reregistration
(under FIFRA, as amended)

Term of Issuance:

Conditional

C712.0 FOR DOGS

Name and Address of Registrant (include ZIP Code):

**Horizon Valley Generics, Inc.
c/o Pyxis Regulatory Consulting, Inc.
4110 136th Street NW.
Gig Harbor, WA 98332**

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with section 3(c)(7)(A) of FIFRA provided that you:

1. Submit and/or cite all data required for registration of your product under section 3(c)(5) of FIFRA when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under section 4 of FIFRA.
2. Submit within 12 months of the date of issuance of this Registration Notice, acceptable guideline studies for Storage Stability study (OPPTS GLN: 830.6317) and Corrosion Characteristics study (OPPTS GLN: 830.6320) for this product.
3. Change the product registration number to "EPA Reg. No. 88052-8"
(continued on page 2)

Signature of Approving Official:

See page 2

Richard Gebken, Product Manager (10)
Insecticide Branch, Registration Division (7505P)

Date:

DEC 13 2012

EPA Form 8570-6

Conditions of acceptance

1. This registration is now time-limited and expires two years from the date of this letter.
2. Please consider limiting the formulations of this product to one basic confidential statement of formula. The Agency may require this in the future and no additional alternate formulations or minor formulation amendments will be approved for this product in the future.
3. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product beginning January 1, 2012.

Please flag any Confidential Business Information as such. Enhanced incident reporting should be submitted to the Product Manager. Quarterly sales information should be submitted to the Registration Division, Immediate Office (attn: Kaitlon Keller).

The following is a list of information that must be included in the quarterly reports for each incident:

EPA Registration Number
Product name (brand name)
Lot #
Where purchased: internet, store, veterinarian
Active Ingredient(s)
Weight range for product

Date on which incident occurred. (mm/dd/yyyy)
State in which the incident occurred. (standard 2 letter abbreviation)
Registrant case #

Species: dog, cat, other (specify)
Breed: (as reported by pet owner)
Age: months or years
Sex: M, F, or neutered
Weight: pounds

Primary Route of Exposure: dermal, oral, other animal, inhalation, other
Body System: neurological, dermatological, GI, respiratory, ocular, other
Major signs noted with separate column for each sign, using standard terminology
Time to Onset: (hours, days)
Treated by veterinarian: yes or no
First time product used: yes or no
Misuse: use on incorrect species, overdose, too frequent dosing, other (describe)
Any known precondition
EPA Severity Code: death, major, moderate, minor
Outcome: died, recovered, still treated, unknown

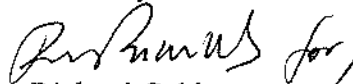
4. Along with the enhanced incident reporting, you must submit an analysis of the incidents seen, to include the following details:

- All incidents should be reported including all minor dermal and ocular irritation reports.
- Summary table for dogs showing number of incidents of each severity code for each route of exposure. Each incident should only be reported once. If one incident has several routes of exposure, the order should be ocular > oral > dermal. In other words, an incident with both oral and dermal exposure would be reported as oral exposure, and an incident with both ocular and oral exposure would be reported as ocular exposure.
- A similar summary table for cats (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure.
- Summary table for dogs and table for cats showing number of incidents that are believed due to secondary exposure (e.g., multi-pet households).
- A summary table for dogs showing number of incidents for each severity code for these age ranges: <3 months, 3-6 months, 6-9 months, 9-12 months, 1 yr, 2 yr, 3 yr, 4 yr, 5 yr, 6 yr, 7 yr, 8 yr, 9 yr, 10 yr, 11 yr, 12 yr, 13 yr, 14 yr, 15 yr, >15 yr.
- A summary table showing the number of dog incidents for each severity code for each pet weight range on the product label.
- A summary table for dog weight showing number of incidents for each product weight range. This table should show number of incidents in dogs weighing less than that product weight range, number of incidents in dogs in lower half of weight range, number of incidents in dogs in upper half of weight range, and dogs weighing more than the product weight range.
- Table showing number of incidents for each dog breed.
- Table showing number of incidents in dogs for each clinical sign.
- Table showing number of incidents in dogs for each organ system.

Report aggregate incidents, but do not combine moderate and minor incidents.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions. If EPA determines that future mitigation measures are necessary for all spot-on products, the Agency will inform registrants and if needed, EPA may take regulatory action. If you have any questions contact Driss Benmhend at 703-308-9525 or by e-mail at: Benmhend.driss@epa.gov.

Sincerely,



Richard Gebken
Product Manager 10,
Insecticide Branch
Registration Division (7505P)

Enclosure: Label Stamped "with Comments"

[Label Directions and Container (Carton) and Package Insert for
0.023 fl. oz. (0.67 mL) (applicators) (pipettes)]
[Label Directions and Container (Carton) and Package Insert for
0.045 fl. oz. (1.34 mL) (applicators) (pipettes)]
[Label Directions for Container (Carton) and Package Insert for
0.091 fl. oz. (2.68 mL) (applicators) (pipettes)]
[Label Directions and Container (Carton) and Package Insert for
0.136 fl. oz. (4.02 mL) (applicators) (pipettes)]

[Optional text appears in brackets – the final label may include some or all optional text on front, back, side, or inside label panels]

[CARTON – 3 x 0.023 FL. OZ. PACKAGE]
[CARTON – 3 x 0.045 FL. OZ. PACKAGE]
[CARTON – 3 x 0.091 FL. OZ. PACKAGE]
[CARTON – 3 x 0.136 FL. OZ. PACKAGE]

C712.0 FOR DOGS

[Alternate Brand Names]

[SpringLine (for dogs & puppies – up to 22 lbs. and 8 weeks or older) – picture of dog in weight class]
[SpringLine (for dogs & puppies – 23-44 lbs. and 8 weeks or older) – picture of dog in weight class]
[SpringLine (for dogs & puppies – 45-88 lbs. and 8 weeks or older) – picture of dog in weight class]
[SpringLine (for dogs & puppies – 89-132 lbs. and 8 weeks or older) – picture of dog in weight class]

[FOR DOGS & PUPPIES – Use only on dogs weighing up to 22 lbs. and 8 weeks or older]

[FOR DOGS & PUPPIES – Use only on dogs weighing 23-44 lbs. and 8 weeks or older]

[FOR DOGS & PUPPIES – Use only on dogs weighing 45-88 lbs. and 8 weeks or older]

[FOR DOGS & PUPPIES – Use only on dogs weighing 89-132 lbs. and 8 weeks or older]

Optional Marketing Claims] Fleas, Ticks, Chewing Lice]

- [Fast-acting, long-lasting, convenient spot treatment for control of fleas, ticks and chewing lice]
- [Waterproof]
- [C712.0 FOR DOGS provides convenient and effective flea, tick, and chewing lice control for dogs and puppies.]
- [Fast acting and long-lasting]
- [Prevents re-infestation]
- [Convenient to use]
- [Kills (newly emerged) adult fleas before they lay eggs]
- [Controls fleas which may cause flea allergy dermatitis]
- [Kills all stages of brown dog ticks (*R. sanguineus*), American dog ticks (*D. variabilis*), lone star ticks (*Amblyomma americanum*), and deer ticks (*Ixodes scapularis*)(which may carry Lyme disease)]
- [Rapidly eliminates infestations with chewing lice]
- [Aids in control of sarcoptic mange infestations]
- [Can be used on breeding, pregnant and lactating bitches]

ACCEPTED
With COMMENTS
In EPA Letter Dated:

DEC 13 2012
Under the Federal Insecticide, Fungicide
and Rodenticide Act, As amended, for the
pesticide Registered under EPA Reg. No:

88052-8

- [Waterproof (water resistant)]
- [Prevents infestation]
- [Kills fleas that may cause (flea allergy dermatitis) (and) (flea bite dermatitis)]
- [Protects for one month]
- [Effective monthly treatment of fleas, ticks and lice]
- [Remains effective after bathing and swimming]
- [Kills ticks that may transmit Lyme disease, Rocky Mountain spotted fever, babesiosis, ehrlichiosis, bartonellosis, hepatozoonosis]
- [(Easy,) (fast,)(effective) control of fleas, ticks and lice]
- [Kills fleas (ticks) (lice)]
- [Kills fleas that may cause anemia]
- [Optional graphics: Picture of Flea]
- [Optional graphics: Picture of tick]
- [Optional graphics: Picture of louse]
- [Contains the proven effective topical fipronil]
- [Contains the proven effective topical fipronil found in Frontline*]
- [Convenient to use]
- [Long lasting]
- [Fast acting]
- [Eliminates infestations with chewing lice]
- [Controls and prevents re-infestation]
- [Kills all stages of deer ticks]
- [Prevents infestations of adult fleas and adult ticks.]
- [Apply monthly]
- [Controls mites that may cause sarcoptic mange]
- [Best results when used monthly (year round)]
- [For year round protection]
- [Kills newly emerged fleas before they lay eggs]
- [Calendar stickers inside]
- 3 Doses
- Controls flea re-infestation for up to one month (4 weeks)
- [Contains (Fipronil) the active ingredient used in Frontline Top Spot® for Dogs]
- [C712.0 FOR DOGS is not manufactured by or distributed by Merial Limited.]
- [Frontline Top Spot® is a registered trademark of Merial Limited.]
- [Contains Fipronil (the active ingredient used in Frontline Top Spot® for Dogs)]
- [Compare to Frontline Top Spot® for Dogs]
- [C712.0 FOR DOGS is not manufactured by or distributed by Merial. Frontline is a registered trademark of Merial]

EPA Reg. No. 88052-I

EPA Est. 74720-DEU-01

ACTIVE INGREDIENT:

Fipronil 9.7%

OTHER INGREDIENTS: 90.3%

TOTAL: 100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

See [back (side) panel and insert] for additional Precautionary and First Aid Statements

NET CONTENTS:

[Three (3) 0.023 fl. oz. (0.67 mL) (applicators) (pipettes)]

[Three (3) 0.045 fl. oz. (1.34 mL) (applicators) (pipettes)]

[Three (3) 0.091 fl. oz. (2.68 mL) (applicators) (pipettes)]

[Three (3) 0.136 fl. oz. (4.02 mL) (applicators) (pipettes)]

[CAT PROHIBITION ICON]



DO NOT USE ON CATS. Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian.

Side Effects. Monitor your dog after application. Side effects may include skin irritation such as redness, scratching or other signs of discomfort. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects occur, consult your veterinarian or the ASPCA Animal Poison Control Center at 1-888-426-4435.

C712.0 FOR DOGS 8 weeks or older

C712.0 FOR DOGS contains the active ingredient fipronil that effectively targets fleas, ticks, and chewing lice. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. **Do not allow children to apply product.** To prevent injury to you and your dog, read entire label and directions on the package insert before each use. Follow all directions and precautionary statements carefully. This product must only be used on dogs. Do not use on rabbits or on other animals.

[Precaucion al consumidor: si usted no puede leer inglés, no use este producto hasta que la etiqueta le haya sido explicada ampliamente. (To the user: If you cannot speak English, do not use this product until the label has been fully explained to you).]

To kill fleas and all stages of brown **dog ticks**, **American dog ticks**, **lone star ticks**, and **deer ticks** (which may carry Lyme disease) and chewing lice, apply this product to dogs and puppies (8 weeks or older) as follows.

To remove and open (applicator) (pipette): See label insert for opening instructions.

INSTRUCTIONS FOR APPLYING PRODUCT

To apply C712.0 for Dogs: Place (applicator) (pipette) tip through dog's hair to the skin level between the shoulder blades. Squeeze (applicator) (pipette), applying entire contents in a single spot to the dog's skin. Avoid superficial application to the dog's hair. Allow area to dry before touching treated area. Only one (applicator) (pipette) per treatment is needed.

OR [Alternate application method]

For dogs & puppies weighting up to 22 lbs. Apply one (applicator) (pipette) from the back of the neck to a point midway between the neck and tail.

OR [Alternate application method]

For dogs & puppies weighting up to 22 lbs. Apply one (applicator) (pipette) starting at the base of the tail moving in a straight line toward head against the hair along the backbone (spine).

C712.0 for Dogs can also be used for the treatment and control of flea, tick, and chewing lice infestations on breeding, pregnant, and lactating bitches. C712.0 for Dogs aids in the control of sarcoptic mange infestations. Multiple monthly treatments are recommended for the elimination of mites.

FREQUENCY OF APPLICATION

When used monthly, C712.0 for Dogs completely controls flea, tick, and chewing lice infestations. Research demonstrates that C712.0 for Dogs kills adult fleas up to three months. Although C712.0 for Dogs can control fleas for up to three months, if there is a high risk of re-infestation or if the dog has fleas which may cause flea allergy dermatitis, a once monthly application may be needed. C712.0 for Dogs kills ticks for at least one month. A once monthly application is recommended where tick control is needed. A once monthly application is recommended where chewing lice are present. C712.0 for Dogs remains effective even after bathing, water immersion, or exposure to sunlight. Do not reapply C712.0 for Dogs for 30 days.

Manufactured for:

Horizon Valley Generics, Inc.
1201 Walnut Street, Suite 2900
Kansas City, Missouri 64106

MADE IN Germany

C712.0 FOR DOGS/ trade name is a registered trademark of Horizon Valley Generics, Inc.
©2012 Horizon Valley Generics, Inc. All rights reserved.

[LABEL DIRECTIONS FOR PACKAGE INSERT –
3 x 0.023 FL. OZ. PACKAGE]
[LABEL DIRECTIONS FOR PACKAGE INSERT –
3 x 0.045 FL. OZ. PACKAGE]
[LABEL DIRECTIONS FOR PACKAGE INSERT –
3 x 0.091 FL. OZ. PACKAGE]
[LABEL DIRECTIONS FOR PACKAGE INSERT –
3 x 0.136 FL. OZ. PACKAGE]

C712.0 FOR DOGS 8 weeks or older

EPA Reg. No. 88052-I

[EPA Est. 74720-DEU-01]

ACTIVE INGREDIENT:

Fipronil 9.7%

OTHER INGREDIENTS: 90.3%

TOTAL: 100.0%

Kills fleas and all stages of brown dog ticks, American dog ticks, lone star ticks, and deer ticks (which may carry Lyme disease) and chewing lice

KEEP OUT OF REACH OF CHILDREN

CAUTION

C712.0 for Dogs contains the active ingredient fipronil that effectively targets fleas, ticks, and chewing lice. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. **Do not allow children to apply product.** To prevent injury to you and your dog, read entire label and directions on the package insert before each use. Follow all directions and precautionary statements carefully. This product must only be used on dogs. Do not use on rabbits or on other animals.

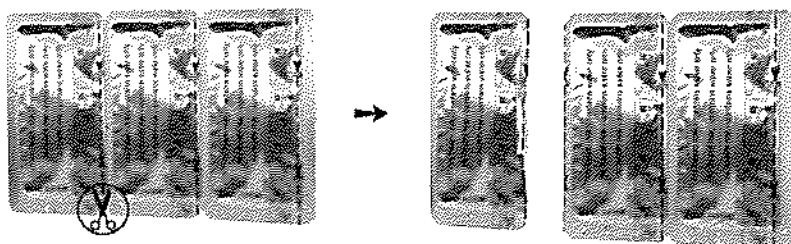
Precaucion al consumidor: si usted no puede leer inglés, no use este producto hasta que la etiqueta le haya sido explicada ampliamente. (To the user: If you cannot speak English, do not use this product until the label has been fully explained to you).

To kill fleas and all stages of **brown dog ticks, American dog ticks, lone star ticks, and deer ticks** (which may carry Lyme disease) and chewing lice, apply this product to dogs and puppies (8 weeks or older) as follows.

To remove and open (applicator) (pipette):

[ILLUSTRATIONS FOR OPENING PRODUCT]

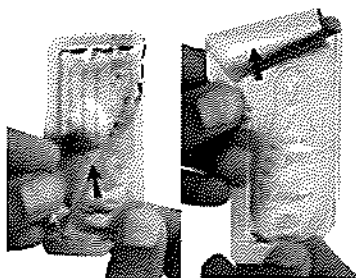
- 1** Cut along scissor cut line to separate unit



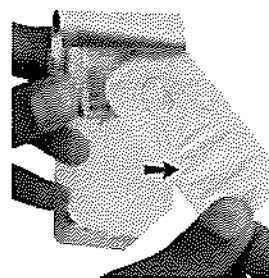
- 2** Turn unit over and cut corner at bulb end



- 3** From cut corner, peel backing completely off from bottom to top



- 4** Remove the applicator



[ILLUSTRATIONS FOR APPLYING PRODUCT]

To apply C712.0 for Dogs: Place (applicator) (pipette) tip through dog's hair to the skin level between the shoulder blades. Squeeze (applicator) (pipette), applying entire contents in a single spot to the dog's skin. Avoid superficial application to the dog's hair. Allow area to dry before touching treated area. Only one (applicator) (pipette) per treatment is needed.

OR [Alternate application method]

For dogs & puppies weighting up to 22 lbs. Apply one (applicator) (pipette) from the back of the neck to a point midway between the neck and tail.

OR [Alternate application method]

For dogs & puppies weighting up to 22 lbs. Apply one (applicator) (pipette) starting at the base of the tail moving in a straight line toward head against the hair along the backbone (spine).

C712.0 for Dogs can also be used for the treatment and control of flea, tick, and chewing lice infestations on breeding, pregnant, and lactating bitches. C712.0 for Dogs aids in the control of sarcoptic mange infestations. Multiple monthly treatments are recommended for the elimination of mites.

FREQUENCY OF APPLICATION

When used monthly, C712.0 FOR DOGS completely controls flea, tick, and chewing lice infestations. Research demonstrates that C712.0 FOR DOGS kills adult fleas up to three

months. Although C712.0 FOR DOGS can control fleas for up to three months, if there is a high risk of re-infestation or if the pet has fleas which may cause flea allergy dermatitis, a once monthly application may be needed. C712.0 FOR DOGS kills ticks for at least one month. A once monthly application is recommended where tick control is needed. A once monthly application is recommended where chewing lice are present. C712.0 FOR DOGS remains effective even after bathing, water immersion, or exposure to sunlight. Avoid contact with treated area until dry. Do not reapply C712.0 FOR DOGS for 30 days.

[CAT PROHIBITION ICON]

DO NOT USE ON CATS. Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian.

Side Effects. Monitor your dog after application. Side effects may include skin irritation such as redness, scratching or other signs of discomfort. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects occur, consult your veterinarian or the ASPCA Animal Poison Control Center at 1-888-426-4435.

[LABEL DIRECTIONS FOR PACKAGE INSERT –
3 x 0.023 FL. OZ. PACKAGE]
[LABEL DIRECTIONS FOR PACKAGE INSERT –
3 x 0.045 FL. OZ. PACKAGE]
[LABEL DIRECTIONS FOR PACKAGE INSERT –
3 x 0.091 FL. OZ. PACKAGE]
[LABEL DIRECTIONS FOR PACKAGE INSERT –
3 x 0.136 FL. OZ. PACKAGE]

C712.0 FOR DOGS

FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

HOTLINE NUMBER: Have the product container or label with you when calling a poison control center, doctor or going for treatment. You may contact the ASPCA Animal Poison Control Center at 1-888-426-4435 for emergency medical treatment information.

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS

CAUTION. Causes moderate eye irritation. Harmful if swallowed. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

HAZARDS TO DOMESTIC ANIMALS

For external use only. Do not use on puppies under 8 weeks of age. Individual sensitivities, while rare, may occur after using any pesticide product. Dogs may experience some temporary irritation at the site of product application. If signs persist, or become more severe within a few days of application, consult a veterinarian. If your dog has an unusual reaction to the initial application, consult a veterinarian before repeating treatment. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated or aged dogs. Call the ASPCA Animal Poison Control Center at 1-888-426-4435 for assistance.

QUESTIONS OR COMMENTS ABOUT THIS PRODUCT

Call the ASPCA Animal Poison Control Center at 1-888-426-4435

[GRAPHICS/PICTURES]

[PRODUCT BAR CODE]

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage. Store unused product in original container only, out of reach of children and animals.

PESTICIDE DISPOSAL. If partly filled, call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

CONTAINER DISPOSAL. If empty: Non refillable container. Do not reuse this container. If empty: Place in trash or offer for recycling if available.

HOW SUPPLIED

C712.0 FOR DOGS is available in convenient sizes for small dogs and puppies 8 weeks or older and up to 22 lbs., medium dogs 23-44 lbs., large dogs 45-88 lbs., and extra-large dogs 89-132 lbs.

up to 22 lbs.	Contains 3 - 0.023 fl. oz. (0.67 mL) (applicators) (pipettes)
23-44 lbs.	Contains 3 - 0.045 fl. oz. (1.34 mL) (applicators) (pipettes)
45-88 lbs.	Contains 3 - 0.091 fl. oz. (2.68 mL) (applicators) (pipettes)
89-132 lbs.	Contains 3 - 0.136 fl. oz. (4.02 mL) (applicators) (pipettes)

WARRANTY

To the extent consistent with applicable law, Horizon Valley Generics, Inc. and/or seller makes no warranty, expressed or implied, concerning the use of this product other than indicated on the label. Buyer assumes all risk of use resulting from the handling of this product. Seller shall return the purchase price or at the election of the seller replace the product.

Manufactured for:

Horizon Valley Generics, Inc.
1201 Walnut Street, Suite 2900
Kansas City, Missouri 64106

[MADE IN Germany]

C712.0 FOR DOGS/ trade name is a registered trademark of Horizon Valley Generics, Inc.

©2012 Horizon Valley Generics, Inc. All rights reserved.

[Text for Back of Blister Pack]

Pictogram with scissors and cut-line (see photo above)

Keep Out of Reach of Children

Read directions before use.

CAUTION

Cat prohibition icon



DO NOT USE ON CATS

Use ONLY on Puppies up to 22 lbs and 8 weeks or older
0.023 fl. oz.

Use ONLY on Dogs 23-44 lbs and 8 weeks or older
0.045 fl. oz.

Use ONLY on Dogs 45-88 lbs and 8 weeks or older
0.091 fl. oz.

Use ONLY on Dogs 89-132 lbs and 8 weeks or older
0.136 fl. oz.

C712.0 for Dogs

Fipronil 9.7%

EPA Reg. No. 88052-I

Lot No.

[Text for Back of Pipette]

Keep Out of Reach of Children

Read directions before use.

CAUTION

DO NOT USE ON CATS

C712.0 for Dogs

Fipronil 9.7%

EPA Reg. No. 88052-I

Lot No.

(Use ONLY on Puppies up to 22 lbs and 8 weeks or older
0.023 fl. oz.)

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0.045 fl. oz.)

(Use ONLY on Dogs 45-88 lbs and 8 weeks or older

0.091 fl. oz.)

(Use ONLY on Dogs 89-132 lbs and 8 weeks or older

0.136 fl. oz.)



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

BARCODE No.: 402805; **DECISION No.:** 465445 **FILE SYMBOL No.:** 88052-I;
PRODUCT NAME: C712.0 for Dogs; **PC Code(s):** 129121; **Action Code:** R310; **FOOD Use:** No

DATE: October 23, 2012

SUBJECT: Product Name: C712.0 for Dogs

FROM: Akiva Abramovitch, Ph.D.
Technical Review Branch / RD (7505P) *JA*

THROUGH: Shyam Mathur, Ph.D.
Product Chemistry Team Leader
Technical Review Branch/RD (7505P) *SPB* *11/5/12*

TO: Driss Benmhend/Richard Gebken, PM 10
Insecticide Branch/ RD (7505C)

Company Name: Horizon Valley Generics, Inc.
Formulation Type: Spot On

INTRODUCTION:

The applicant has submitted an application for registration of a new end use product containing fipronil at 9.7%. In support of the registration application, the registrant has submitted product chemistry data corresponding to guideline 830 series group A & B data in MRIDs 488455-01 through-03. Also submitted a CSF of the basic formulation dated May 17, 2012 along with the product label. TRB has been asked to determine the acceptability of the product chemistry data and the proposed CSF dated May 17, 2012.

SUMMARY OF FINDINGS:

1. Name of Active Ingredient: Fipronil 9.7%.
2. Has the registrant claimed substantial similarity to a registered product?
☐ Yes; ☒ No; ☐ NA; If yes give the registration number of the cited product.
3. All the source materials for the active ingredients are derived from the registered sources:
☒ Yes; ☐ No.
4. All inert ingredients have been screened by ILAB and found to be approved for the proposed labeled uses: ☒ Yes; ☐ No.

BARCODE No.: 402805; **DECISION No.:** 465445 **FILE SYMBOL No.:** 88052-I;

PRODUCT NAME: C712.0 for Dogs; **PC Code(s):** I29121; **Action Code:** R3I0; **FOOD Use:** No

5. Confidential Statement of Formula(s):

☒ Basic Dated: May 17, 2012;

6. Product label

- a. Ingredient statement: Nominal concentration of AI listed on CSF(s) concur with product label (PR Notice 91-2).

☒ Yes, if not, explain below:

Is the sub statement in compliance with PR Notice 97-6 (inert ingredient vs other ingredient)?

☒ Yes; ☐ No; if not, explain below:

Metallic equivalent: ☐ Yes ☒ NA;

Soluble arsenic: ☐ Yes ☒ NA

Isomeric ratios: ☐ Yes ☒ NA

Acid equivalent: ☐ Yes ☒ NA; {name} acid equivalent = xx %

- b. Health related sub statements: Product contains?

Petroleum distillate at > 10%: ☐ Yes ☒ No ☐ NA

Methanol at > 4%: ☐ Yes ☒ No ☐ NA

Sodium nitrate/Sodium nitrite ☐ Yes ☒ No ☐ NA

- c. Physical chemical hazard statement: Product label requires a statement per 40 CFR §156.78 for: flammability, explosive potential or electric insulator breakdown?

☐ Yes ☒ No

Is the sub statement in compliance with PR Notice 98-6 (Total Release Fogger)?

☐ Yes, ☐ No, ☒ NA, if not, explain below:

- d. Label requires an additional Storage and Disposal statement:

☐ Yes ☒ No

BARCODE No.: 402805; **DECISION No.:** 465445 **FILE SYMBOL No.:**88052-I;

PRODUCT NAME: C712.0 for Dogs; **PC Code(s):** 129121; **Action Code:** R310; **FOOD Use:** No

7. Group A: Product Chemistry Data

TRB's determination of the acceptability for the proposed product is listed in the tables below.

Guideline No.	Study Title		Data submitted		TRB's Assessment of Data	MRID Nos.
			Yes	No		
830.1550	Product Identity & Composition		X		A	488455-01
830.1600	Description of materials used to produce the product		X		A	488455-01
830.1650	Description of formulation process		X		A	488455-01
830.1670	Discussion on the formation of impurities		X		A	488455-01
830.1700	Preliminary analysis		X		NA	
830.1750	Certified limits (158.350)	Standard certified Limits	X		A	488455-01
		Proposed Limits			NA	
		Justification for wider limits			NA	
830.1800	Enforcement analytical method		X		A (HPLC method)	488455-01

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver Request, I = In Progress, NA = Not Applicable; U = Upgradeable

OPPTS GUIDELINE No. 830.1800: ANALYTICAL METHODS TO VERIFY CERTIFIED LIMITS:

The determination of fipronil in C712:O is carried out using high performance liquid chromatography using an isocratic method employing a reverse phase C18 column with UV-VIS detection at 215 nm.

BARCODE No.: 402805; **DECISION No.:** 465445 **FILE SYMBOL No.:**88052-1;

PRODUCT NAME: C712.0 for Dogs; **PC Code(s):** 129121; **Action Code:** R310; **FOOD Use:** No
8. Group B:

Guideline No.	Study Title	Value or Qualitative Description	TRB's Assessment of Data	MRID Nos.
830.6303	Physical State	Pale yellow liquid	A	488455-02
830.6315	Flammability	None	A	488455-02
830.6316	Explodability	NA, not considered to be potentially explosive	A	488455-02
830.7000	pH	5.1 at 25 C	A	488455-02
830.7300	Density (units)	1.025 g/cm ³ at 20C 8.55 lb/gal	A	488455-02

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver request,
NA = Not applicable, I = In progress, U = Upgradeable

CONCLUSIONS:

TRB has reviewed the CSF(s) and product chemistry data for the proposed end use product and has concluded:

1. The proposed CSF for the basic formulation dated May 17, 2012 is acceptable. The nominal concentration of propanil agrees with the label claim of 9.7%. All the ingredients in the formulations have been approved for the uses cited on the label.
2. The data submitted corresponding to guidelines 830.1550 (product identity and composition), 830.1600 (description of materials used to produce the product) , 830.1650 (description of formulation process), 830.1670 (discussion on the formation of impurity), 830.1750 (certified limits), and 830.1800 (enforcement analytical method) are acceptable.
3. The product chemistry data submitted corresponding to guidelines 830.6302 (color), 830.6303 (physical state), 830.6304 (odor), 830.6314 (oxidation/reduction), 830.6315 (flammability), 830.6316 (explodability), 830.7000 (pH), 830.7100 (viscosity), and 830.7300 (density) are acceptable.
4. The storage stability (guideline 830.6317) and corrosion characteristics (guideline 830.6320) studies were not submitted. These physical/chemical properties are required and it is recommended that observations should be made at 0, 3, 6, 9, and 12 month intervals.
5. The proposed label was screened as it pertains to the product chemistry requirements. The review of the proposed label and uses are the purview of the RM team.

Efficacy Review

Date: October 31, 2012

Efficacy Reviewer: Clayton Myers, Ph.D., Entomologist, RD-IB
mvers.clayton@epa.gov
703-347-8874



10-31-12

Risk Manager Rev.: Driss Benmhend

Products: C712.0 for Dogs

EPA Reg. #: 88052-I

A.I.'s: Fipronil (9.7%)

Decision #s: 465445

DP #s: 402909

Submission: R310, New Products, RD Science Review

MRIDs: Cited: Cite-all for efficacy, Fipronil

GLP: N/A

Submission:

The registrant is applying for a new fipronil pet spot-on product, and is citing the entire fipronil efficacy database, with offers to pay to numerous data owners.

Overall Review of Label Claims and Directions:

Based upon the established fipronil efficacy database, all proposed efficacy claims on this product are acceptable with the exception of the following:

"Kills ticks that may transmit vector borne diseases" Open ended claims such as this that pertain to *any* disease are problematic. The label should list and specifically enumerate the diseases, which occur in the US, would be vectored by the tick(s) being controlled. This would also apply to any open-ended claims associated with other pests listed on the label.

"Prevents reinfestation" This claim is only applicable to adult fleas and ticks—because the product does not contain an IGR, no claims are allowed that would imply breaking of the pest life cycle by killing flea larvae/eggs, for example. The claim should be qualified to specifically claim prevention of reinfestation from other adult fleas.

"Controls mites that may cause sarcoptic mange" Must be revised to "aids in control".



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

CHILD-RESISTANT PACKAGING REVIEW
Technical Review Branch

IN 6/19/2012 OUT 7/23/2012

RD, TRB, Reviewed by Rosalind L. Gross 7/23/2012

EPA Reg. No. or File Symbol 88502-I & 88502-O

DP Barcode DP402905, 402913

Decision # 465445, 465446

EPA Petition or EUP No. _____

Date Division Received 5/30/12, 5/30/12

Type Product(s) Insecticide (flea product)

Data Accession No(s). _____

Product Mgr./Chemical Review Mgr/Contact Person RM 10 Driss Benmhend
Division RD

Product Name(s) C712.0 for Dogs, C712.0 for Cats

Company Name(s) Horizon Valley Generics, Inc.

Submission Purpose Review of CRP studies to determine if they are adequate to support CRP certification for these products

Active Ingredient(s), PC code, & % Fipronil 9.7%

Summary of Findings

In conclusion all the requirements for CRP have been met for EPA
Registration No. 88502-I & 88502-O. The directions on opening the package

given to consumers must be identical to those given to the seniors during testing (see packaging section below). For details see Analysis of Data and Conclusions section below.

Should any human experience/epidemiological evidence indicate a problem once the product is in the marketplace, the Agency reserves the right to reexamine this data comprehensively and to question the child resistance of the package involved.

Package

The package is a pipette in a blister. The pipette has clear plastic front and foil backing. The blister is the Child-Resistant Packaging, CRP. The blister backing is PET/AL/PET/PE 12/12/12/75, which appears as a foil color. The blister front is PET/PP/PE transp. LDPE 350/100/75, which appears as a clear color. Three blisters are attached to each other to form one card. There are 5 fill volumes 0.67ml, 1.34ml, 2.68ml, 4.02ml, and 0.5ml.

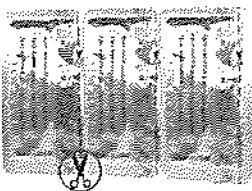
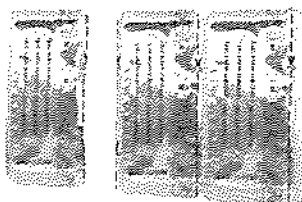

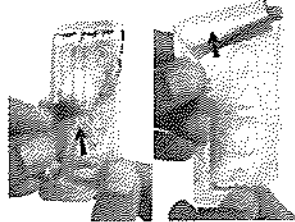
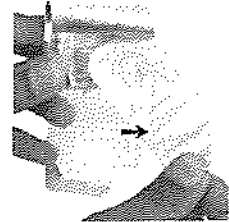
The Senior Adult Use Effectiveness Testing, SAUE, directions on the back of the blister are a pictorial showing the separation of one of the three attached blisters and removing the pipette from the blister that repeats for the height of the blister and a dashed line with a picture of a scissors to the right of the pictorial showing where to separate one of the three attached blisters (see picture below). In addition to the SAUE directions on the back of the blister, there are also SAUE directions in a leaflet that were given to the test subjects. There is a set of instructions used for all 5 fill volumes, which is referred to in this review as Package Instructions for SAUE Testing Set 2 (see picture below for set of SAUE Testing directions). EPA Registration No. 88052-I is for fill volumes 0.67ml, 1.34ml, 2.68ml, 4.02ml. EPA Registration No. 88052-O is fill volume 0.5ml.



Back of Blister with Opening Instructions

Opening Instructions from Package Leaflet

OPENING INSTRUCTIONS FOR USE

- 1** Cut along scissor cut line to separate unit


- 2** Turn unit over and cut corner at bulb end

- 3** From cut corner, peel backing completely off from bottom to top

- 4** Remove the applicator


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Package Instructions for SAUE Testing Set 2

Toxicity

The toxicity of the product is based on the toxicity of Fipronil. The toxic or harmful amount of Fipronil for an 11.4 kg child is 2.5mg/kg times 11.4kg, which equals **28.5mg**. Access to a toxic or harmful amt = **28.5mg** = 28.5mg divided by [1030mg/ml x 0.097 Fipronil] = **0.29ml** for **EPA REG No. 88502-I and 88502-O**.

A child failure is access to one blister of any size equal to or greater than 0.29ml for EPA REG No. 88502-I and 88502-O.

Failure

For the purposes of CRP testing EPA REG No. 88502-I and 88502-O **a child failure is access to one blister** for all sizes. Access to one blister is more than a toxic or harmful amount of Fipronil (28.5mg) for all sizes.

Child Failure is defined as access to one blister, any breach, rip, tear, hole, or penetration of the blister, any visible incision or opening of the blister, any leakage of placebo from blister during or after test, or any partial or complete access to the placebo (water).

Senior Failure is failure to access the blister in the prescribed test time of 5 minutes for the first package or 1 minute for the second package, or inability to remove the pipette in the blister in condition suitable for intended use or removal of the pipette in the blister resulting in significant exposure to pipette contents.

Analysis of Data and Conclusion

The CRP certifications were dated May 29, 2012. These May 29, 2012 CRP certifications for EPA REG No. 88502-I and 88502-O are acceptable. The labels for EPA REG No. 88502-I (0.67ml, 1.34ml, 2.68ml, 4.02ml) and 88502-O (0.5ml) submitted May 29, 2012 use the same SAUE directions that are on the back of the blister and the Package Instructions for SAUE Testing **Set 2** that were given to the seniors during CRP testing (see packaging section for exact instructions).

Provided EPA REG No. **88502-I and 88502-O** are being packaged into the CRP blister in strips of three blisters per card by Klocke Verpackungs-Service GMBH in Germany the data matrix citations for MRID 48703501, 48703502, 48703503, 48703504, and 48652701 for EPA REG No. **88502-I** and MRID 48771101 for EPA REG No. **88502-O** may be used to demonstrate the CRE requirements in 16 CFR 1700.20 and SAUE effectiveness specifications in 16 CFR 1700.15(b)(2)(i) when tested in accordance with 16 CFR 1700.20. MRID 48703501, 48703502, 48703503, 48703504, and 48652701 for EPA REG No. **88502-I** and MRID 48771101 for EPA REG No. **88502-O** indicate the 0.67ml, 1.34ml, 2.68ml, 4.02ml, and 0.5ml sizes meet the CRE requirements in 16 CFR 1700.20 and SAUE effectiveness specifications in 16 CFR

1700.15(b)(2)(i) when tested in accordance with 16 CFR 1700.20.

For the results for the 0.67, 1.34, 4.02, and 0.5ml sizes see MRID 48703501, 48703502, 48703503, 48703504, and 48771101 in review by Rosalind L. Gross April 27, 2012 [DP397839, 400331, 397834, 400678; EPA REG No. 88051-E and 88051-R]. The results for 2.68ml size see MRID 48652701 in review by Rosalind L. Gross April 19, 2012 [DP398108, 399748, 398115, 399746, 398123, 399747, 398262, 399749, 399560, 399565; EPA Registration No. 88052-G, 88052-R, 88052-E, 88052-L, 88052-A, 88052-T].

In conclusion all the requirements for CRP have been met for EPA Registration No. 88502-I and 88502-O. The directions on opening the package given to consumers must be identical to those given to the seniors during testing (see packaging section).

Should any human experience/epidemiological evidence indicate a problem once the product is in the marketplace, the Agency reserves the right to reexamine this data comprehensively and to question the child resistance of the package involved.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Horizon Valley Generics c/o Pyxis Regulatory Consulting Inc., 4110 136th St NW, Gig Harbor WA (253) 853-7369	EPA Registration Number/File Symbol 88052-
Active Ingredient(s) and/or representative test compound(s) Imidacloprid	Date 5/29/12
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Residential Indoor	Product Name C712.0 for Dogs

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

<input type="checkbox"/> I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	<input checked="" type="checkbox"/> I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).
--	---

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature <i>Ann M Tillman</i>	Date 5/29/12	Typed or Printed Name and Title Ann M. Tillman, Agent
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PRIA 2 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

3/23/09

21 Day Screen Start Date: 5/30/12

Experts In-Processing Signature: Elizabeth Nguyen Date 6/1/12

Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date _____

EPA Reg. Number: <u>88052-I</u>		EPA Receipt Date: <u>5/30/12</u>							
Items for Review			Yes	No	N/A*				
1	Application Form (EPA Form 8570-1)(link to form) signed & complete including package type		✓						
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4) (Link to form)		✓						
	a) All inerts (link to http://www.epa.gov/opprd001/inerts/), including fragrances, approved for the proposed uses (see Footnote A)	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="width: 50%; text-align: center;">yes</th> <th style="width: 50%; text-align: center;">no</th> </tr> <tr> <td style="text-align: center;">X</td> <td></td> </tr> </table>	yes	no	X				
yes	no								
X									
3	Certification with Respect to Citation of Data (EPA Form 8570-34) (Link to form) completed and signed (N/A if 100% repack)		✓						
	Certificate and data matrix consistent		✓						
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="width: 50%; text-align: center;">yes</th> <th style="width: 50%; text-align: center;">no</th> </tr> <tr> <td></td> <td></td> </tr> </table>	yes	no					
yes	no								
	If applicable, is there a letter of Authorization for exclusive use only.								
4	Formulator's Exemption Statement (EPA Form 8570-27) (Link to form) completed and signed (N/A if source is unregistered or applicant owns the technical)		✓						
5	Data Matrix (EPA Form 8570-35) (Link to form) both internal and external copies (PR 98-5) (Link to PR 98-5) completed and signed (N/A if 100% repack)		✓						
	a) Selective Method (Fee category experts use)	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="width: 50%; text-align: center;">yes</th> <th style="width: 50%; text-align: center;">no</th> </tr> <tr> <td style="text-align: center;">✓</td> <td></td> </tr> </table>	yes	no	✓				
yes	no								
✓									
b) Cite-All (Fee category experts use)	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="width: 50%; text-align: center;">yes</th> <th style="width: 50%; text-align: center;">no</th> </tr> <tr> <td></td> <td></td> </tr> </table>	yes	no						
yes	no								
c) Applicant owns all data (Fee category experts use)	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="width: 50%; text-align: center;">yes</th> <th style="width: 50%; text-align: center;">no</th> </tr> <tr> <td></td> <td></td> </tr> </table>	yes	no						
yes	no								
6	5 Copies of Label (link to http://www.epa.gov/oppfead1/labeling/lrm/) (Electronic labels on CD are encouraged and guidance is available)(link to http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels)		✓						

7	Is the data package consistent with PR Notice 86-5 (link to PRN 86-5)	X		
8	Notice of Filing (link to http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm) included with petitions (link to http://www.epa.gov/pesticides/regulating/tolerances.htm)			✓
9	If applicable for conventional applications, reduced risk rationale (link to http://www.epa.gov/opprd001/workplan/reducedrisk.html)			✓
10	Required Data (link to http://www.epa.gov/pesticides/regulating/data_requirements.htm) and/or data waivers. See Footnote C.			
	a) List study (or studies) not included with application			

Comments:

- * N.I. + % composition added to offer.
- * CSF : Inerts approved for non-food use.
- * Data package approved.
- * Registrant consult contacted.
- * Tack approved.

NRID: 488455

* N/A – Not Applicable

lk / S-4813
/ AB

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses. If an unapproved inert is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses even if a **product is currently registered** by consulting the inert Web

site [link to <http://www.epa.gov/oppr001/inerts/lists.html>] and if the inert is not approved, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient**. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch1@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch [Link to http://www.epa.gov/oppbppd1/biopesticides/contacts_bppd.htm].

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information [link to <http://www.epa.gov/oppr001/inerts/tips.pdf>] must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R311, R312 or R313), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

May 31, 2012

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-465445
EPA File Symbol or Registration Number: 88052-I
Product Name: C712.0 FOR DOGS
EPA Receipt Date: 30-May-2012
EPA Company Number: 88052
Company Name: HORIZON VALLEY GENERICS, INC

ANN M. TILLMAN
PYXIS REGULATORY CONSULTING, INC
HORIZON VALLEY GENERICS, INC
4110 136TH ST. NW
GIG HARBOR, WA 98332-

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R310

NEW PRODUCT;NON-FAST TRACK (INCLUDES REVIEWS OF PRODUCT
CHEMISTRY;ACUTE TOXICITY;PUBLIC HEALTH PEST EFFICACY);

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee
Ombudsman at (703) 308-9362.

Sincerely,

A handwritten signature in black ink, appearing to be "M. Tillman".

Front End Processing Staff
Information Technology & Resources Management Division

Fee for Service

{917696}~

This package includes the following

☒ New Registration

☐ Amendment

☒ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ____

for Division

☐ AD

☐ BPPD

☒ RD

Risk Mgr.

10

Receipt No.

S-

917696

EPA File Symbol/Reg. No.

88052-I

Pin-Punch Date:

5/30/2012

☐ This item is NOT subject to FFS action.

Action Code:

Requested:

R310

Granted:

R310

Amount Due: \$ 4807⁰⁰

Parent/Child Decisions:

88052-I

88052-1

☐ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer:

[Signature]

Date: 5/31/12

Remarks:

Receipt for Section 3

S: 917696

Resubmission: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☒ Yes ☐ No

Application Type: New Registration

Billable: ☒ Yes ☐ No

Company: 88052 HORIZON VALLEY GENERICS, INC V

Risk Manager: Registration Division, Risk Management Team 10

Product #: 88052-1 Product Name: C712.0 FOR DOGS

Override#

Me Too Section3: 55331-3 Me Too Product Name: FRONTLINE TOP SPOT FOR DOGS

Application Date: 29-May-2012 

OPP Rec'd Date: 30-May-2012 

Front End Date: 31-May-2012 

Risk Manager Send Date: 

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐ New Ingredient: ☐

Receipt Description:

Application for registration of a new end use product.

New Ingredient Request Date:

New Ingredient Received Date:

Form A: ☐ Signature Date:

Form B: ☐ Signature Date:

Print Letter

Enter More Information

Tracking

Receipt Content

Study

CSF

View/Edit

Emma Becker

From: paygovadmin@mail.doc.twai.gov
Sent: Tuesday, May 29, 2012 10:06 AM
To: Emma Becker
Subject: Pay.gov Payment Confirmation: PRIA Service Fees

Your payment has been submitted to Pay.gov and the details are below. If you have any questions regarding this payment, please contact Pay.gov Customer Service by phone at (800) 624-1373 or by email at pay.gov.clev@clev.frb.org.

Application Name: PRIA Service Fees
Pay.gov Tracking ID: 256R52LV
Agency Tracking ID: 74317990S92
Transaction Type: Sale
Transaction Date: May 29, 2012 1:06:05 PM

Account Holder Name: Ann Tillman
Transaction Amount: \$4,807.00
Billing Address: 4110 136th St NW
City: Gig Harbor
State/Province: WA
Zip/Postal Code: 98332
Country: USA
Card Type: AmericanExpress
Card Number: *****1031

Decision Number:
Registration Number:
Company Name: Horizon Valley Generics
Company Number: 880S2
Action Code: R310

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.

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United States
Environmental Protection Agency
Washington, DC 20460

☒ Registration
☐ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number Horizon Valley Generics Inc./88052	2. EPA Product Manager R. Gebken	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Horizon Valley Generics Inc./C712.0 for Dogs	PM# 10	
5. Name and Address of Applicant (Include ZIP Code) Horizon Valley Generics Inc. c/o Pyxis Regulatory Consulting Inc. 4110 136th St. NW Gig Harbor, WA 98332 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) [b](i), my product is similar or identical in composition and labeling to: EPA Reg. No. 65331-3 Product Name Frontline Top Spot for Dogs	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input checked="" type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional pages if necessary. (For section I and Section II.)

This application falls under Category R310 because it is an application for registration of a new end use product substantially similar in composition and use to a registered product (review of data within RD). This application is linked to a secondary application. The fee due which has been paid is \$4,807 with a PRIA decision time line of 6 months.

Section - III

1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input checked="" type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted			
If "Yes" Unit Packaging wgt. 0.023, 0.045, 0.091, 0.136	No. per container 3	If "Yes" Package wgt.	No. per container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 0.089, 0.135, 0.273, 0.408 fl. oz.	5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other on box and on insert inside box	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Ann M. Tillman	Title Agent	Telephone No. (Include Area Code) (253) 853-7369
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Agent	
4. Typed Name Ann M. Tillman	5. Date 5/29/12	

Pyxis REGULATORY CONSULTING, INC.

4110 136th St. NW
Gig Harbor, WA 98332

Phone: 253-853-7369
Fax: 253-853-5516
www.PyxisRC.com

May 29, 2012

OVERNIGHT DELIVERY

Richard Gebken (PM 10)
Document Processing Desk (REGFEE)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

RE: Horizon Valley Generics, Inc.
C712.0 for Dogs (EPA File Symbol 88052-)
Application for New Pesticide Registration
PRIA Category R310, Primary Application

Dear Mr. Gebken,

On behalf of Horizon Valley Generics, Inc., we are submitting an application for registration of C712.0 for Dogs, an end use product containing the active ingredient fipronil.

Please note that C712.0 for Dogs is the identical formulation as C712.0 for Cats (EPA File Symbol 88052-pending) for which an application for registration is submitted with this application. Product-specific data being submitted with this application for registration of C712.0 for Dogs (primary application) support the concurrent application for registration of C712.0 for Cats (secondary application)

In support of this application, we submit the following documents:

1. Application for a New Pesticide Registration (EPA Form 8570-1)
2. Confidential Statement of Formula (EPA Form 8570-4)
3. Three (3) Copies of the Proposed Labeling for C712.0 for Dogs
4. A CD containing an electronic version of the label
5. Certification with Respect to Label Integrity
6. Agency Internal Use Copy of the Data Matrix
7. Public File Copy of the Data Matrix
8. Certification with Respect to Citation of Data (EPA Form 8570-34)
9. Formulator's Exemption Statement (EPA Form 8570-27)
10. Child Resistant Packaging Certifications
11. Copy of the PRIA payment from pay.gov
12. Copy of the cover letter submitted with the application for registration of C712.0 for Cats
13. Letter of Authorization
14. Letter of authorization from sponsor of CRP testing
15. Product Specific Data (3 copies each):

Volume 1	830.1550, 830.1600, 830.1650, 830.1670, 830.1750, 830.1800	Tillman, A. M. Product Identity and Composition, Description of the Materials Used, Description of the Formulation Process, Discussion of the Formation of Impurities, Certified Limits, and Enforcement Analytical Method for C712.0. <i>Contains Confidential Business Information.</i>
Volume 2	830.6302, 830.6303, 830.6304, 830.6314, 830.6315, 830.7000, 830.7100, 830.7300	Miller, R. L. Physical and Chemical Characteristics of C712.0
Volume 3	830.6313, 830.6316, 830.6317, 830.6319, 830.6320, 830.6321, 830.7520	Tillman, A. M. Waiver Requests for Physical and Chemical Properties for C712.0.

Horizon Valley Generic, Inc.'s C712.0 for Dogs qualifies for the Formulator's Exemption for fipronil generic data requirements. Horizon Valley Generics, Inc. is using the cite-all method for product specific data support. As per EPA's interpretations of 40 CFR Parts 152.90 - 152.96, Horizon Valley Generics, Inc. submitted notices of intent to apply and offers to pay to all companies on the March 29, 2012 Data Submitter's List.

Horizon Valley Generics, Inc. believes this application falls under Category R310 (46: New end-use product; requires review of data package within RD). This application is linked to the secondary applications for registration of C712.0 for Cats. The fee due which has been paid is \$4,807 with a PRIA decision time line of 6 months because the CRP data that supports this registration is still being reviewed by EPA.

We trust you will find this application complete. However, please feel free to contact me by email at Ann@PyxisRC.com or by phone at (253) 853-7369 if you have any questions or need any additional information.

Sincerely,



Ann M. Tillman

Enclosures

**Child Resistant Packaging Certification
For Horizon Valley Generic, Inc.'s C712.0 for Dogs
(EPA Registration No. 88052-)**

Registrant: Horizon Valley Generics, Inc.
1201 Walnut Street, Suite 2900
Kansas City, Missouri 64106

I certify that the packaging that will be used for this product meets the standards of 40 CFR 157.32.

EPA Registration No. 88052-[pending], C712.0 for Dogs is **filled and packaged by Firma Klocke Verpackungs-Service GmbH**. The package consists of a placebo filled pipette with a clear plastic front and foil backing that is contained in a blister. The blister has a clear plastic front (PET/PP/PE transp. LDPE – 350/100/75) and a foil backing (PET/AL/PET/PE – 12/12/12/75). Three blisters are connected to each other. The blister is the child-resistant packaging. The pipette has four fill levels, which are 0.023 fl. oz. (0.67 mL), 0.045 fl. oz. (1.34 mL), 0.091 fl. oz. (2.68 mL) and 0.136 fl. oz. (4.02 mL). Child Resistant Packaging, CRP, testing was conducted on the blister with a placebo filled pipette at each of the four fill levels:

- 0.023 fl. oz. (0.67 mL) (MRID 48703501 – NCRT Child study no. 10-030 and NCRT Senior 11-044),
- 0.045 fl. oz. (1.34 mL) (MRID 48703502 – NCRT Child study no. 10-032 and NCRT Senior 11-045),
- 0.091 fl. oz. (2.68 mL) (MRID 48652701 – NCRT Child study no. 10-034 and NCRT Senior 11-046):
- 0.136 fl. oz. (4.02 mL) (MRID 48703503 – NCRT Child study no. 10-036 and NCRT Senior 11-047).


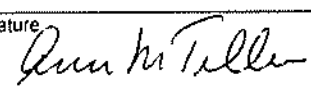
I realize that additional CRP testing may be required if EPA Registration No. 88052-[pending], C712.0 for Dogs is **not filled and packaged by Firma Klocke Verpackungs-Service GmbH on the same equipment as the samples tested** (0.023 fl. oz. (0.67 mL) (MRID 48703501 – NCRT Child study no. 10-030 and NCRT Senior 11-044), 0.045 fl. oz. (1.34 mL) (MRID 48703502 – NCRT Child study no. 10-032 and NCRT Senior 11-045), 0.091 fl. oz. (2.68 mL) (MRID 48652701 – NCRT Child study no. 10-034 and NCRT Senior 11-046); 0.136 fl. oz. (4.02 mL) (MRID 48703503 – NCRT Child 10-036 and NCRT Senior 11-047)). Further, any change in CRP opening instructions from those used in testing, color, size, and/or materials for the CRP may result in additional CRP testing for EPA Registration No. 88052-[pending], C712.0 for Dogs.



Ann M. Tillman
Agent for Horizon Valley Generics, Inc.
Pyxis Regulatory Consulting, Inc.

May 29, 2012
Date

Form approved. OMB No. 2070-0060, 2070-0057, 2070-0107, 2070-0122, 2070-0164.

 <div style="text-align: center;"> <p>United States Environmental Protection Agency Washington, DC 20460</p> <p>Formulator's Exemption Statement (40 CFR 152.85)</p> </div>								
<p>Applicant's Name and Address</p> <p>Horizon Valley Generics, Inc. 1201 Walnut Street, Suite 2900 Kansas City, MO 64106</p>	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="padding: 2px 5px;">EPA File Symbol/Registration Number</td> <td style="padding: 2px 5px;">88052-</td> </tr> <tr> <td style="padding: 2px 5px;">Product Name</td> <td style="padding: 2px 5px;">C712.0 for Dogs</td> </tr> <tr> <td style="padding: 2px 5px;">Date of Confidential Statement of Formula (EPA Form 8570-4)</td> <td style="padding: 2px 5px;">05/17/2012</td> </tr> </table>		EPA File Symbol/Registration Number	88052-	Product Name	C712.0 for Dogs	Date of Confidential Statement of Formula (EPA Form 8570-4)	05/17/2012
EPA File Symbol/Registration Number	88052-							
Product Name	C712.0 for Dogs							
Date of Confidential Statement of Formula (EPA Form 8570-4)	05/17/2012							
<p>As an authorized representative of the applicant for registration of the product identified above, I certify that:</p> <p>(1) This product contains the following active ingredient(s):</p> <p style="margin-left: 40px;">Fipronil</p> <p>(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).</p> <p>(3) Indicate by checking (A) or (B) below which paragraph applies:</p> <p><input checked="" type="checkbox"/> (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).</p> <p style="text-align: center;">OR</p> <p><input type="checkbox"/> (B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.</p> <p>(4) The following active ingredients in this product qualify for the formulator's exemption.</p>								
<p>Source</p>								
<p>Active Ingredient</p> <p>Fipronil</p>	<p>Product Name</p> <div style="background-color: black; height: 20px; width: 100%;"></div> <div style="background-color: black; height: 20px; width: 100%;"></div> <div style="background-color: black; height: 20px; width: 100%;"></div> <div style="background-color: black; height: 20px; width: 100%;"></div> <div style="background-color: black; height: 20px; width: 100%;"></div> <div style="background-color: black; height: 20px; width: 100%;"></div>	<p>Registration Number</p> <div style="background-color: black; height: 20px; width: 100%;"></div> <div style="background-color: black; height: 20px; width: 100%;"></div> <div style="background-color: black; height: 20px; width: 100%;"></div> <div style="background-color: black; height: 20px; width: 100%;"></div> <div style="background-color: black; height: 20px; width: 100%;"></div> <div style="background-color: black; height: 20px; width: 100%;"></div>						
<p>Signature</p> 	<p>Name and Title</p> <p>Ann M. Tillman, Agent</p>	<p>Date</p> <p>5/29/12</p>						

EPA Form 8570-27 (Rev. 06-2004)


Copy 1 - EPA
Copy 2 - Applicant copy

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date <u>May 29, 2012</u>		EPA Reg. No./File Symbol <u>88052-</u>		Page <u>1</u> of 7	
Applicant's/Registrant's Name & Address Horizon Valley Generics, Inc. 1201 Walnut Street, Suite 2900 Kansas City, MO 64106		Product C710.2 for Dogs			
Ingredient <u>Fipronil (CAS No. 120068-37-3)</u>					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Product Specific Data Requirements					
830.1550	Product Identity and Composition	Volume 1	Horizon Valley Generics, Inc.	OWN	
830.1600	Description of Materials Used to Produce the Product	Volume 1	Horizon Valley Generics, Inc.	OWN	
830.1620	Description of Production Process				Not required ¹
830.1650	Description of Formulation Process	Volume 1	Horizon Valley Generics, Inc.	OWN	
830.1670	Discussion of Formation of Impurities	Volume 1	Horizon Valley Generics, Inc.	OWN	
830.1700	Preliminary Analysis				Not Required ²
830.1750	Certified Limits	Volume 1	Horizon Valley Generics, Inc.	OWN	
830.1800	Enforcement Analytical Method	Volume 1	Horizon Valley Generics, Inc.	OWN	
830.6302	Color	Volume 2	Horizon Valley Generics, Inc.	OWN	
830.6303	Physical State	Volume 2	Horizon Valley Generics, Inc.	OWN	
830.6304	Odor	Volume 2	Horizon Valley Generics, Inc.	OWN	
830.6313	Stability to Normal and Elevated Temperatures, Metals, and Metal Ions				Not Required ³
830.6314	Oxidation/Reduction: Chemical Incompatibility	Volume 2	Horizon Valley Generics, Inc.	OWN	Data
830.6315	Flammability	Volume 2	Horizon Valley Generics, Inc.	OWN	
830.6316	Explosibility	Volume 3	Horizon Valley Generics, Inc.	OWN	Waiver ⁴
Signature 			Name and Title Ann M. Tillman, Consultant		Date May 29, 2012


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Applicant's/Registrant's Name & Address Horizon Valley Generics, Inc. 1201 Walnut Street, Suite 2900 Kansas City, MO 64106			Product C710.2 for Dogs		
Ingredient <u>Fipronil (CAS No. 120068-37-3)</u>					
Guideline Reference Number	Guideline Study Name	MRIQ Number	Submitter	Status	Note
830.6317	Storage Stability	Volume 3	Horizon Valley Generics, Inc.	OWN	PR-92-5 ⁵
830.6319	Miscibility				Not required ⁶
830.6320	Corrosion Characteristics	Volume 3	Horizon Valley Generics, Inc.	OWN	PRN 92-53 ⁵
830.6321	Dielectric Breakdown Voltage				Not required ⁷
830.7000	pH	Volume 2	Horizon Valley Generics, Inc.	OWN	
830.7050	UV/Visible Absorption				Not Required ⁸
830.7100	Viscosity	Volume 2	Horizon Valley Generics, Inc.	OWN	
830.7200	Melting Point/Melting Range				Not Required ⁸
830.7220	Boiling Point/Boiling Range				Not Required ⁸
830.7300	Density/Relative Density/Bulk Density	Volume 2	Horizon Valley Generics, Inc.	OWN	
830.7370	Dissociation Constants in Water				Not Required ⁸
830.7520	Particle size, fiber length, diameter distribution	Volume 3	Horizon Valley Generics, Inc.	OWN	Waiver ⁹
830.7550	Partition Coefficient (n-octanol/water), Shake Flask Method				Not Required ⁸
830.7560	Partition Coefficient (n-octanol/water), Generator Column Method				See 830.7560
830.7570	Partition Coefficient (n-octanol/water), Estimation by Liquid Chromatography				See 830.7560
Signature 			Name and Title Ann M. Tillman, Consultant		Date May 29, 2012

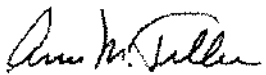
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DATA MATRIX


Date May 29, 2012			EPA Reg. No./File Symbol 88052-		Page 3 of 7
Applicant's/Registrant's Name & Address Horizon Valley Generics, Inc. 1201 Walnut Street, Suite 2900 Kansas City, MO 64106			Product C710.2 for Dogs		
Ingredient Fipronil (CAS No. 120068-37-3)					
Guideline Reference Number	Guideline Study Name	MRIO Number	Submitter	Status	Note
830.7840	Water Solubility: Column Elution Method; Shake Flask Method				Not Required ⁸
830.7860	Water Solubility, Generator Column Method				See 830.7840
830.7950	Vapor Pressure				Not Required ⁸
870.1100	Acute Oral Toxicity: Rat	Cite-All		PAY	
870.1200	Acute Dermal Toxicity: Rat	Cite-All		PAY	
870.1300	Acute Inhalation Toxicity: Rat				Waiver ¹⁰
870.2400	Primary Eye Irritation: Rabbit	Cite-All		PAY	
870.2500	Primary Dermal Irritation	Cite-All		PAY	
870.2600	Dermal Sensitization	Cite-All		PAY	
870.7200	Companion Animal Safety	Cite-All		PAY	
810.3300	Product Performance	Cite-all		PAY	
US 16 CFR § 1700	Child Resistant Packaging Study	48703501 48703502 48703503 48703504 48652701	Chanelle Pharmaceutical, Inc. Chanelle Pharmaceutical, Inc. Chanelle Pharmaceutical, Inc. Chanelle Pharmaceutical, Inc. Horizon Valley Generics, Inc.	PER PER PER PER PER	
Signature 			Name and Title Ann M. Tillman, Consultant		Date May 29, 2012

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Date <u>May 29, 2012</u>		EPA Reg. No./File Symbol <u>88052-</u>		Page <u>7</u> of 7	
Applicant's/Registrant's Name & Address Horizon Valley Generics, Inc. 1201 Walnut Street, Suite 2900 Kansas City, MO 64106		Product C710.2 for Dogs			
Ingredient <u>Fipronil (CAS No. f20068-37-3)</u>					
Guideline Reference Number	Guideline Study Name	MRIO Number	Submitter	Status	Note
Generic Data Requirements					
Horizon Valley Generic, Inc.'s C712.0 for Dogs qualifies for the Formulator's Exemption for fipronil generic data requirements.					
Product Specific Data Requirements					
Horizon Valley Generic, Inc. will make offers-to-pay to the following companies on the March 29, 2012 Data Submitters List for fipronil.					
		Cite-All	Syngenta Crop Protection LLC	PAY	
		Cite-All	The Scotts Company	PAY	
		Cite-All	Bayer Cropscience LP	PAY	
		Cite-All	Bayer Environmental Science	PAY	
		Cite-All	Whitmire Micro-Gen Research Laboratories	PAY	
		Cite-All	Pfizer, Inc.	PAY	
		Cite-All	Virbac AH, Inc.	PAY	
		Cite-All	Sergeant's Pet Care Products, Inc.	PAY	
		Cite-All	The Hartz Mountain Corp.	PAY	
		Cite-All	Reckitt Benckiser LLC	PAY	
Signature 			Name and Title Ann M. Tillman, Consultant		Date May 29, 2012

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DATA MATRIX

Date May 29, 2012		EPA Reg. No./File Symbol 88052-		Page 5 of 7	
Applicant's/Registrant's Name & Address Horizon Valley Generics, Inc. 1201 Walnut Street, Suite 2900 Kansas City, MO 64106		Product C710.2 for Dogs			
Ingredient Fipronil (CAS No. 120068-37-3)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
		Cite-All	Cheminova A/S	PAY	
		Cite-All	J. J. Mauget Co.	PAY	
		Cite-All	BASF Corp.	PAY	
		Cite-All	Chemsico	PAY	
		Cite-All	Makhteshim Chemical Works Ltd.	PAY	
		Cite-All	Gharda Chemicals Limited	PAY	
		Cite-All	Control Solutions Inc.	PAY	
		Cite-All	Virbac	PAY	
		Cite-All	Combat Insect Control Systems	PAY	
		Cite-All	Pyrethroid Working Group	PAY	
		Cite-All	Merial Limited	PAY	
		Cite-All	Spray Drift Task Force	PAY	
		Cite-All	Cheminova Inc.	PAY	
		Cite-All	Outdoor Residential Exposure Task Force	PAY	
Signature 			Name and Title Ann M. Tillman, Consultant		Date May 29, 2012

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WASHINGTON, D.C. 20460

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DATA MATRIX

Date May 29, 2012

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Applicant's/Registrant's Name & Address

Horizon Valley Generics, Inc.
1201 Walnut Street, Suite 2900
Kansas City, MO 64106

Product

C710.2 for Dogs

Ingredient Fipronil (CAS No. 120068-37-3)

Guideline Reference Number	Guideline Study Name	MRIO Number	Submitter	Status	Note
		Cite-All	Agricultural Reentry Task Force	PAY	
		Cite-All	Ambrands	PAY	
		Cite-All	Innovative Pest Control Products	PAY	
		Cite-All	FIFRA Endangered Species Task Force	PAY	
		Cite-All	Irvita Plant Protection N.V.	PAY	
		Cite-All	Residential Exposure Joint Venture	PAY	
		Cite-All	Agricultural Handlers Exposure Task Force	PAY	
		Cite-All	Sharda USA LLC	PAY	
		Cite-All	Fidopharm, Inc.	PAY	
		Cite-All	Norbrook, Inc.	PAY	
		Cite-All	Loradochem, Inc.	PAY	
		Cite-All	Lnouvel, Inc.	PAY	
		Cite-All	Zhejiang Hisun Pharmaceuticals Co., Ltd.	PAY	
Signature				Name and Title	Date
				Ann M. Tillman, Consultant	May 29, 2012

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date May 29, 2012

EPA Reg. No./File Symbol 88052-

Page 7 of 7

Applicant's/Registrant's Name & Address

Horizon Valley Generics, Inc.
1201 Walnut Street, Suite 2900
Kansas City, MO 64106

Product

C710.2 for Dogs

Ingredient Fipronil (CAS No. 120068-37-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
		Cite-All	Argite – Fipronil LLC	PAY	
		Cite-All	Firponex Solutions Inc.	PAY	
		Cite-All	Virbac S. A.	PAY	
		Cite-All	Raymat Materials Inc.	PAY	
		Cite-All	Chanelle Pharmaceuticals Manufacturing	PAY	
		Cite-All	Tru Prodigy Animal Health, LLC	PAY	

Signature



Name and Title

Ann M. Tillman, Consultant

Date

May 29, 2012

Endnotes for Data Matrix for C712.0 for Dogs

- ¹ **830.1620** - These data are not required for the registration of an end-use product. See **830.1650** for formulation process information.
- ² **830.1700** - This product does not consist solely of the technical grade active ingredient (TGAI) and is not produced by an integrated system, therefore, per OPPTS **830.1700**, these data are not required.
- ³ **830.6313** - These data are not required for registration of an end-use product.
- ⁴ **830.6316** - Neither the active ingredient, fipronil, nor any of the inert ingredients in C712.0 for Dogs contains the chemical bonds or functional groups associated with chemicals that are explosive. Therefore, a waiver from this data requirement is requested.
- ⁵ **830.6317, 830.6320** -Per PR Notice 92-5, storage stability and corrosion characteristic data are not required to be submitted unless specifically requested by the Agency.
- ⁶ **830.6319** - This data requirement is required when the product is an emulsifiable liquid and to be diluted with petroleum solvents. The C712.0 for Dogs is not an emulsifiable liquid to be diluted with petroleum solvents and therefore this data requirement is not applicable.
- ⁷ **830.6321** - This product is not proposed for use around electrical equipment. Therefore, these data are not applicable.
- ⁸ **830.7050, 830.7200, 830.7220, 830.7370, 830.7550-7570, 830.7840-7860, 830.7950** - These data are not required for registration of an end-use product.
- ⁹ **830.7520** - Horizon Valley Generics Inc. is seeking a waiver for this data requirement for C712.0 for Dogs because the product is not a fibrous material or a water-insoluble material.
- ¹⁰ **870.1300** - Per a pre-registration meeting with EPA on September 22, 2010 with Horizon Valley Generics, EPA indicated that an inhalation toxicity study is not required for C712.0. A waiver request is provided in MRID 48652806.

U.S. EPA
Office of Pesticide Programs
Registration Division
1915 M Street, NW
Washington, DC 20548
Phone: (703) 849-8000
Fax: (703) 849-8001
E-mail: registration@epa.gov
Web: www.epa.gov/pesticides
U.S. EPA
Office of Pesticide Programs
Registration Division
1915 M Street, NW
Washington, DC 20548
Phone: (703) 849-8000
Fax: (703) 849-8001
E-mail: registration@epa.gov
Web: www.epa.gov/pesticides

version: 9/11/02

PROPOSED LABEL		
EPA Registration #	Date Submitted to EPA	Electronic file name
088052-xxxxx	May 29, 2012	088052-xxxxx.20120529.C712.0 for Dogs label.v1.pdf

Ann M. Fuller

May 29, 2012
Date

[illegible]

There is an **ELECTRONIC LABEL** for this action

You can use Acrobat to compare the e-label to the previous version (and find the changes). You can also use Acrobat to mark-up the e-label with your comments.

If e-label was submitted via

CD-ROM with paper application

then you will find e-label in

Electronic Label Library

If the e-label is not found in the ELL then it was probably not named correctly and could not be entered into the ELL. However, the file can be retrieved from the CD which is retained by the Front End.

or

If e-label was submitted via

XML E-Submission (no paper)

then you will find e-label in

Documentum

See overview of processing e-labels on other side of this sheet.

If you have any questions on e-labels, please contact one of your division e-label experts:

AD	Willie Abney	308-1689
	Renae Whitaker	308-7003
	Tracy Lantz	308-6415
BPPD		
RD	Tom Harris	308-9423



Horizon Valley Generics, Inc.

December 17, 2010

To Whom It May Concern:

RE: Letter of Authorization

Dear Sir or Madam:

Please let this letter serve to confirm that Pyxis Regulatory Consulting, Inc. is authorized to act as agents for Horizon Valley Generics, Inc (EPA Company Number [pending]), before the U.S. Environmental Protection Agency and state governmental agencies in all matters regarding our pesticide registrations pursuant to the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136 et seq. and state law.

If you have any questions, please do not hesitate to contact me.

Sincerely,

Bénédicte Deminière
CEO

cc: Pyxis Regulatory Consulting, Inc.



KLOCKE VERPACKUNGS-SERVICE GMBH

May 9, 2012

Richard Gebken (PM 10)
Document Processing Desk
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

Subject: Letter of Authorization
Horizon Valley Generics, Inc.
Applications for Registration: C712.0 for Dogs, and C712.0 for Cats

Dear Mr. Gebken:

Please let this letter serve to notify the U.S. Environmental Protection Agency that Klocke Verpackungs-Service GMBH (Klocke) authorizes Horizon Valley Generics, Inc. (HVG) (1201 Walnut Street, Suite 2900, Kansas City, MO 64106, EPA Company Number 88052) to cite Child Resistant Packaging (CRP) data in support of applications for registrations of C712.0 for Dogs and C712.0 for Cats. These CRP data are proprietary to Klocke, and this letter does not confer ownership or exclusive rights of the data; other companies may rely on these data if authorized by Klocke. Below is a list of the CRP studies and MRID Numbers that HVG is authorized to cite.

Citation	MRID Number
Novosad, M. (2011) Child Resistant Packaging Study: Thermoforme Blister Pack for Pipettes of 0.50 mL Capacity; Report No. KVS-201106	48771101
Novosad, M. (2011) Child Resistant Packaging Study: Thermoforme Blister Pack for Pipettes of 0.67 mL Capacity; Report No. KVS-201107.	48703501
Novosad, M. (2011) Child Resistant Packaging Study: Thermoforme Blister Pack for Pipettes of 1.34 mL Capacity; Report No. KVS-201108.	48703502
Novosad, M. (2011) Child Resistant Packaging Study: Thermoforme Blister Pack for Pipettes of 2.68 mL Capacity; Report No. KVS-201104.	48652761
Novosad, M. (2011) Child Resistant Packaging Study: Thermoforme Blister Pack for Pipettes of 4.02 mL Capacity; Report No. KVS-201109	48703503
Novosad, M. (2011) Child Resistant Packaging Study Test Summary Report: Thermoforme Blister Pack for Pipettes of 0.5 mL Capacity, 0.67 mL Capacity, 1.34 mL Capacity, 2.68 mL Capacity, 4.02 mL Capacity; Report No. KVS-201110	48703504

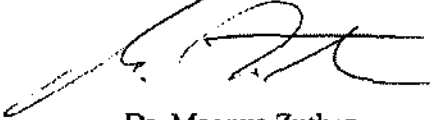
Klocke
Verpackungs-Service GmbH
Max-Becker-Str. 8
D-76356 Weingarten
Fax: 07244/61-0
Fax: 07244/61-1170
Internet: www.klocke.com

Bankverbindungen:
HypoVereinsbank Karlsruhe, BLZ 68020286, Kto.-Nr. 352955442
IBAN: DE81660202860352955442, SWIFT (BIC): HYVEDE33
Volksbank Weingarten-Walzachtal eG, BLZ 66061724, Kto.-Nr. 30218000
IBAN: DE03660617240030218000, SWIFT (BIC): GENODE61WGA
BW Bank, BLZ 60050101, Kto.-Nr. 4022875
IBAN: DE90500501010004022875, SWIFT (BIC): SOLADE61
Banque Palatine
IBAN: FR7740978000590375033R00148, SWIFT (BIC): BSPFRPPXXX

Geschäftsführer:
Carsten Klocke / Dr. Magnus Zuther
Erfüllungsort: Weingarten/Baden
Gerichtsstand Karlsruhe
Registergericht: Amtsgericht
Mannheim HRB 105401
Ust-Id-Nr.: DE143584364
Steuer-Nr.: 34423/20401

Please direct any questions concerning this letter or the information contained herein to Richard Schwemmer at +33 3 88 45 33 13 or via email at richard.schwemmer@klocke.com.

Sincerely,



Dr. Magnus Zuther
C.E.O.

Klocke
Verpackungs-Service GmbH
Max-Becker-Str. 6
D-76356 Weingarten
Fon: 07244/81-0
Fax: 07244/81-1170
Internet: www.klocke.com

Bankverbindungen:
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IBAN: DE81680202860352955442, SWIFT (BIC): HYVEDEMM475
Volksbank Weingarten-Walzachtal eG, BLZ 69061724, Kto.-Nr. 30218000
IBAN: DE03690617240030218000, SWIFT (BIC): GENODE31WGA
SW Bank, BLZ 60060101, Kto.-Nr. 4022675
IBAN: DE060601010004022675, SWIFT (BIC): SOLADEST
Banque Palatine
IBAN: FR7740978000590375033R00148, SWIFT (BIC): BSPFFRPPXXX

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Gerichtsstand: Karlsruhe
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Mannheim HRB 105401
Ust-Id-Nr.: DE143584364
Steuer-Nr.: 34423/20401

- [Label Directions and Container (Carton) and Package Insert for 0.023 fl. oz. (0.67 mL) (applicators) (pipettes)]
- [Label Directions and Container (Carton) and Package Insert for 0.045 fl. oz. (1.34 mL) (applicators) (pipettes)]
- [Label Directions for Container (Carton) and Package Insert for 0.091 fl. oz. (2.68 mL) (applicators) (pipettes)]
- [Label Directions and Container (Carton) and Package Insert for 0.136 fl. oz. (4.02 mL) (applicators) (pipettes)]

[Optional text appears in brackets – the final label may include some or all of the optional text on front, back, side, or inside label panels]

- [FRONT PANEL OF CARTON – 3 x 0.023 FL. OZ. PACKAGE]
- [FRONT PANEL OF CARTON – 3 x 0.045 FL. OZ. PACKAGE]
- [FRONT PANEL OF CARTON – 3 x 0.091 FL. OZ. PACKAGE]
- [FRONT PANEL OF CARTON – 3 x 0.136 FL. OZ. PACKAGE]

C712.0 FOR DOGS

[Alternate Brand Names]

- [SpringLine (for dogs & puppies – up to 22 lbs. and 8 weeks or older) – picture of dog in weight class]
- [SpringLine (for dogs & puppies – 23-44 lbs. and 8 weeks or older) – picture of dog in weight class]
- [SpringLine (for dogs & puppies – 45-88 lbs. and 8 weeks or older) – picture of dog in weight class]
- [SpringLine (for dogs & puppies – 89-132 lbs. and 8 weeks or older) – picture of dog in weight class]

[FOR DOGS & PUPPIES – Use only on dogs weighing up to 22 lbs. and 8 weeks or older]

[FOR DOGS & PUPPIES – Use only on dogs weighing 23-44 lbs. and 8 weeks or older]

[FOR DOGS & PUPPIES – Use only on dogs weighing 45-88 lbs. and 8 weeks or older]

[FOR DOGS & PUPPIES – Use only on dogs weighing 89-132 lbs. and 8 weeks or older]

Optional Marketing Claims [Fleas, Ticks, Chewing Lice]

- [Fast-acting, long-lasting, convenient spot treatment for control of fleas, ticks and chewing lice]
- [Kills ticks that may transmit vector borne diseases]
- [Waterproof]
- [C712.0 FOR DOGS provides convenient and effective flea, tick, and chewing lice control for dogs and puppies.]
- [Fast acting and long-lasting]
- [Prevents re-infestation]
- [Convenient to use]
- [Kills (newly emerged) adult fleas before they lay eggs]
- [Controls fleas which may cause flea allergy dermatitis]
- [Kills all stages of brown dog ticks (*R. sanguineus*), American dog ticks (*D. variabilis*), lone star ticks (*Amblyomma americanum*), and deer ticks (*Ixodes scapularis*)(which may carry Lyme disease)]
- [Rapidly eliminates infestations with chewing lice]
- [Aids in control of sarcoptic mange infestations]



- [Can be used on breeding, pregnant and lactating bitches]
- [Waterproof (water resistant)]
- [Prevents infestation]
- [Kills fleas that may cause (flea allergy dermatitis) (and) (flea bite dermatitis)]
- [Protects for one month]
- [Effective monthly treatment of fleas, ticks and lice]
- [Remains effective after bathing and swimming]
- [Kills the vectors that may transmit; Lyme disease, Rocky Mountain spotted fever, babesiosis, ehrlichiosis, bartonellosis, hepatozoonosis]
- [(Easy,) (fast,)(effective) control of fleas, ticks and lice]
- [Kills fleas (ticks) (lice)]
- [Kills fleas that may cause anemia]
- [Optional graphics: Picture of Flea]
- [Optional graphics: Picture of tick]
- [Optional graphics: Picture of louse]
- [Contains the proven effective topical fipronil]
- [Contains the proven effective topical fipronil found in Frontline*]
- [Convenient to use]
- [Long lasting]
- [Fast acting]
- [Eliminates infestations with chewing lice]
- [Controls and prevents re-infestation]
- [Kills all stages of deer ticks]
- [Prevents infestations]
- [Apply monthly]
- [Controls mites that may cause sarcoptic mange]
- [Best results when used monthly (year round)]
- [For year round protection]
- [Kills newly emerged fleas before they lay eggs]
- [Calendar stickers inside]
- 3 Doses
- Controls flea re-infestation for up to one month (4 weeks)
- [Contains (Fipronil) the active ingredient used in Frontline Top Spot® for Dogs]
- [C712.0 FOR DOGS is not manufactured by or distributed by Merial Limited.]
- [Frontline Top Spot® is a registered trademark of Merial Limited.]
- [Contains Fipronil (the active ingredient used in Frontline Top Spot® for Dogs)]
- [Compare to Frontline Top Spot® for Dogs]
- [C712.0 FOR DOGS is not manufactured by or distributed by Merial. Frontline is a registered trademark of Merial]

EPA Reg. No. 88052-xxxx

EPA Est. 74720-DEU-01

ACTIVE INGREDIENT:

Fipronil 9.7%

INERT INGREDIENTS: 90.3%

TOTAL: 100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

See [back (side) panel and insert] for additional Precautionary and First Aid Statements

NET CONTENTS:

[Three (3) 0.023 fl. oz. (0.67 mL) (applicators) (pipettes)]

[Three (3) 0.045 fl. oz. (1.34 mL) (applicators) (pipettes)]

[Three (3) 0.091 fl. oz. (2.68 mL) (applicators) (pipettes)]

[Three (3) 0.136 fl. oz. (4.02 mL) (applicators) (pipettes)]

[CAT PROHIBITION ICON]

DO NOT USE ON CATS. Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian.

Side Effects. Monitor your dog after application. Side effects may include skin irritation such as redness, scratching or other signs of discomfort. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects occur, consult your veterinarian or us at xxx-xxx-xxxx.

[BACK PANEL OF CARTON – 3 x 0.023 FL. OZ. PACKAGE]

[BACK PANEL OF CARTON – 3 x 0.045 FL. OZ. PACKAGE]

[BACK PANEL OF CARTON – 3 x 0.091 FL. OZ. PACKAGE]

[BACK PANEL OF CARTON – 3 x 0.136 FL. OZ. PACKAGE]

C712.0 FOR DOGS 8 weeks or older

C712.0 FOR DOGS contains the active ingredient fipronil that effectively targets fleas, ticks, and chewing lice. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. **Do not allow children to apply product.** To prevent injury to you and your dog, read entire label and directions on the package insert before each use. Follow all directions and precautionary statements carefully. This product must only be used on dogs. **Do not use on rabbits or on other animals.**

[Precaucion al consumidor: si usted no puede leer inglés, no use este producto hasta que la etiqueta le haya sido explicada ampliamente. (To the user: If you cannot speak English, do not use this product until the label has been fully explained to you).]

To kill fleas and all stages of **brown dog ticks, American dog ticks, lone star ticks, and deer ticks** (which may carry Lyme disease) and chewing lice, apply this product to dogs and puppies (8 weeks or older) as follows.

To remove and open (applicator) (pipette): See label insert for opening instructions.

INSTRUCTIONS FOR APPLYING PRODUCT

To apply C712.0 for Dogs: Place (applicator) (pipette) tip through dog's hair to the skin level between the shoulder blades. Squeeze (applicator) (pipette), applying entire contents in a single spot to the dog's skin. Avoid superficial application to the dog's hair. Allow area to dry before touching treated area. Only one (applicator) (pipette) per treatment is needed.

OR [Alternate application method]

For dogs & puppies weighting up to 22 lbs. Apply one (applicator) (pipette) from the back of the neck to a point midway between the neck and tail.

OR [Alternate application method]

For dogs & puppies weighting up to 22 lbs. Apply one (applicator) (pipette) starting at the base of the tail moving in a straight line toward head against the hair along the backbone (spine).

C712.0 for Dogs can also be used for the treatment and control of flea, tick, and chewing lice infestations on breeding, pregnant, and lactating bitches. C712.0 for Dogs aids in the control of sarcoptic mange infestations. Multiple monthly treatments are recommended for the elimination of mites.

FREQUENCY OF APPLICATION

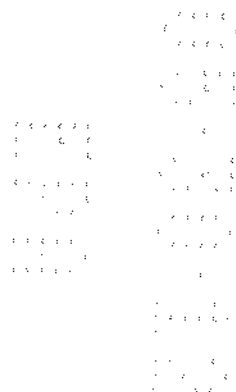
When used monthly, C712.0 for Dogs completely controls flea, tick, and chewing lice infestations. Research demonstrates that C712.0 for Dogs kills adult fleas up to three months. Although C712.0 for Dogs can control fleas for up to three months, if there is a high risk of re-infestation or if the dog has fleas which may cause flea allergy dermatitis, a once monthly application may be needed. C712.0 for Dogs kills ticks for at least one month. A once monthly application is recommended where tick control is needed. A once monthly application is recommended where chewing lice are present. C712.0 for Dogs remains effective even after bathing, water immersion, or exposure to sunlight. Do not reapply C712.0 for Dogs for 30 days.

Manufactured for:

Horizon Valley Generics, Inc.
1201 Walnut Street, Suite 2900
Kansas City, Missouri 64106

MADE IN Germany

C712.0 FOR DOGS/ trade name is a registered trademark of Horizon Valley Generics, Inc.
©2012 Horizon Valley Generics, Inc. All rights reserved.



[FRONT OF LABEL DIRECTIONS FOR PACKAGE INSERT –
3 x 0.023 FL. OZ. PACKAGE]
[FRONT OF LABEL DIRECTIONS FOR PACKAGE INSERT –
3 x 0.045 FL. OZ. PACKAGE]
[FRONT OF LABEL DIRECTIONS FOR PACKAGE INSERT –
3 x 0.091 FL. OZ. PACKAGE]
[FRONT OF LABEL DIRECTIONS FOR PACKAGE INSERT –
3 x 0.136 FL. OZ. PACKAGE]

C712.0 FOR DOGS 8 weeks or older

EPA Reg. No. 88052-xxxx

EPA Est. 74720-DEU-01

ACTIVE INGREDIENT:

Fipronil 9.7%

INERT INGREDIENTS: 90.3%

TOTAL: 100.0%

Kills fleas and all stages of brown dog ticks, American dog ticks, lone star ticks, and deer ticks (which may carry Lyme disease) and chewing lice

KEEP OUT OF REACH OF CHILDREN

CAUTION

C712.0 for Dogs contains the active ingredient fipronil that effectively targets fleas, ticks, and chewing lice. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. **Do not allow children to apply product.** To prevent injury to you and your dog, read entire label and directions on the package insert before each use. Follow all directions and precautionary statements carefully. This product must only be used on dogs. **Do not use on rabbits or on other animals.**

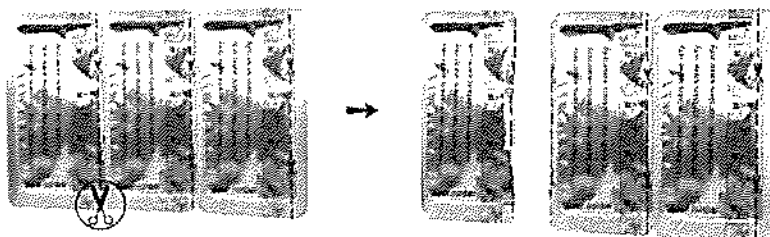
Precaucion al consumidor: si usted no puede leer inglés, no use este producto hasta que la etiqueta le haya sido explicada ampliamente. (To the user: If you cannot speak English, do not use this product until the label has been fully explained to you).

To kill fleas and all stages of **brown dog ticks, American dog ticks, lone star ticks, and deer ticks** (which may carry Lyme disease) and chewing lice, apply this product to dogs and puppies (8 weeks or older) as follows.

To remove and open (applicator) (pipette):

[ILLUSTRATIONS FOR OPENING PRODUCT]

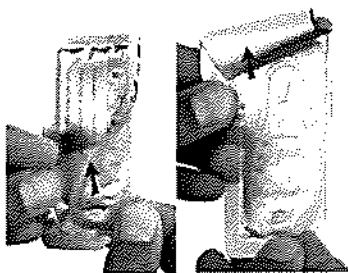
- 1** Cut along scissor cut line to separate unit



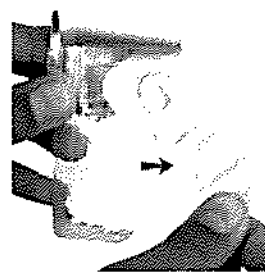
- 2** Turn unit over and cut corner at bulb end



- 3** From cut corner, peel backing completely off from bottom to top



- 4** Remove the applicator



[ILLUSTRATIONS FOR APPLYING PRODUCT]

To apply C712.0 for Dogs: Place (applicator) (pipette) tip through dog's hair to the skin level between the shoulder blades. Squeeze (applicator) (pipette), applying entire contents in a single spot to the dog's skin. Avoid superficial application to the dog's hair. Allow area to dry before touching treated area. Only one (applicator) (pipette) per treatment is needed.

OR [Alternate application method]

For dogs & puppies weighting up to 22 lbs. Apply one (applicator) (pipette) from the back of the neck to a point midway between the neck and tail.

OR [Alternate application method]

For dogs & puppies weighting up to 22 lbs. Apply one (applicator) (pipette) starting at the base of the tail moving in a straight line toward head against the hair along the backbone (spine).

C712.0 for Dogs can also be used for the treatment and control of flea, tick, and chewing lice infestations on breeding, pregnant, and lactating bitches. C712.0 for Dogs aids in the control of sarcoptic mange infestations. Multiple monthly treatments are recommended for the elimination of mites.

FREQUENCY OF APPLICATION

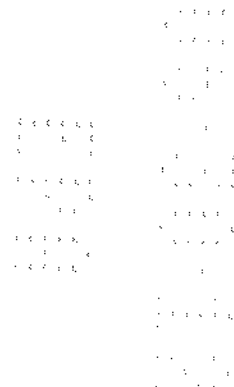
When used monthly, C712.0 FOR DOGS completely controls flea, tick, and chewing lice infestations. Research demonstrates that C712.0 FOR DOGS kills adult fleas up to three

months. Although C712.0 FOR DOGS can control fleas for up to three months, if there is a high risk of re-infestation or if the pet has fleas which may cause flea allergy dermatitis, a once monthly application may be needed. C712.0 FOR DOGS kills ticks for at least one month. A once monthly application is recommended where tick control is needed. A once monthly application is recommended where chewing lice are present. C712.0 FOR DOGS remains effective even after bathing, water immersion, or exposure to sunlight. Avoid contact with treated area until dry. Do not reapply C712.0 FOR DOGS for 30 days.

[CAT PROHIBITION ICON]

DO NOT USE ON CATS. Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian.

Side Effects. Monitor your dog after application. Side effects may include skin irritation such as redness, scratching or other signs of discomfort. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects occur, consult your veterinarian or us at xxx-xxx-xxxx.



[BACK OF LABEL DIRECTIONS FOR PACKAGE INSERT –
3 x 0.023 FL. OZ. PACKAGE]
[BACK OF LABEL DIRECTIONS FOR PACKAGE INSERT –
3 x 0.045 FL. OZ. PACKAGE]
[BACK OF LABEL DIRECTIONS FOR PACKAGE INSERT –
3 x 0.091 FL. OZ. PACKAGE]
[BACK OF LABEL DIRECTIONS FOR PACKAGE INSERT –
3 x 0.136 FL. OZ. PACKAGE]

C712.0 FOR DOGS

FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation persists.

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes.

Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice.

Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

HOTLINE NUMBER: Have the product container or label with you when calling a poison control center, doctor or going for treatment. You may contact us at xxx-xxx-xxxx for emergency medical treatment information.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS

CAUTION. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

HAZARDS TO DOMESTIC ANIMALS

For external use only. Do not use on puppies under 8 weeks of age. Individual sensitivities, while rare, may occur after using any pesticide product. Dogs may experience some temporary irritation at the site of product application. If signs persist, or become more severe within a few days of application, consult a veterinarian. If your dog has an unusual reaction to the initial application, consult a veterinarian before repeating treatment. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated or aged dogs. Call 1-xxx-xxx-xxxx for 24-hour assistance.

QUESTIONS OR COMMENTS ABOUT THIS PRODUCT

Call xxx-xxx-xxxx

[GRAPHICS/PICTURES]

[PRODUCT BAR CODE]

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage. Store unused product in original container only, out of reach of children and animals.

PESTICIDE DISPOSAL. If partly filled, call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

CONTAINER DISPOSAL. If empty: Non refillable container. Do not reuse this container. If empty: Place in trash or offer for recycling if available.

HOW SUPPLIED

C712.0 FOR DOGS is available in convenient sizes for small dogs and puppies 8 weeks or older and up to 22 lbs., medium dogs 23-44 lbs., large dogs 45-88 lbs., and extra-large dogs 89-132 lbs.

up to 22 lbs.	Contains 3 - 0.023 fl. oz. (0.67 mL) (applicators) (pipettes)
23-44 lbs.	Contains 3 - 0.045 fl. oz. (1.34 mL) (applicators) (pipettes)
45-88 lbs.	Contains 3 - 0.091 fl. oz. (2.68 mL) (applicators) (pipettes)
89-132 lbs.	Contains 3 - 0.136 fl. oz. (4.02 mL) (applicators) (pipettes)

WARRANTY

To the extent consistent with applicable law, Horizon Valley Generics, Inc. and/or seller makes no warranty, expressed or implied, concerning the use of this product other than indicated on the label. Buyer assumes all risk of use resulting from the handling of this product. Seller shall return the purchase price or at the election of the seller replace the product.

Manufactured for:

Horizon Valley Generics, Inc.
1201 Walnut Street, Suite 2900
Kansas City, Missouri 64106

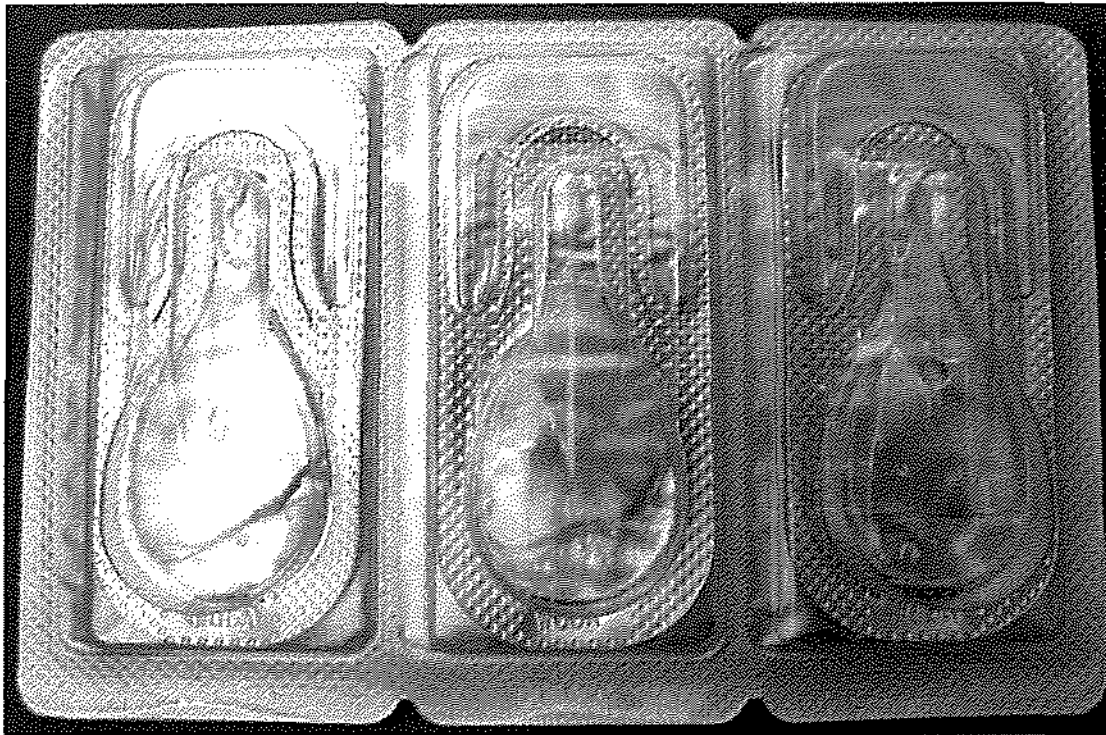
MADE IN Germany

C712.0 FOR DOGS/ trade name is a registered trademark of Horizon Valley Generics, Inc.

©2012 Horizon Valley Generics, Inc. All rights reserved.



[Pictogram of Front of Blister With Opening Instructions – NOT PART OF LABEL]



[Pictogram of Back of Blister With Opening Instructions – NOT PART OF LABEL]



[Text for Back of Blister Pack]

Keep Out of Reach of Children

See full label for additional instructions

CAUTION

Only for Dogs & Puppies

C712.0 for Dogs

EPA Reg. No. 88052-xxxx

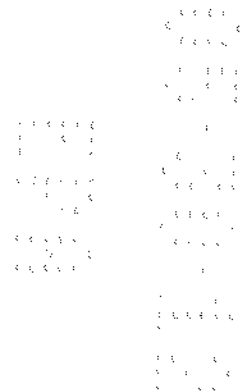
Lot No.

[0.023 fl. oz.]

[0.045 fl. oz.]

[0.091 fl. oz.]

[0.136 fl. oz.]



- [Label Directions and Container (Carton) and Package Insert for 0.023 fl. oz. (0.67 mL) (applicators) (pipettes)]
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- [FRONT PANEL OF CARTON – 3 x 0.091 FL. OZ. PACKAGE]
- [FRONT PANEL OF CARTON – 3 x 0.136 FL. OZ. PACKAGE]

C712.0 FOR DOGS

[Alternate Brand Names]

- [SpringLine (for dogs & puppies – up to 22 lbs. and 8 weeks or older) – picture of dog in weight class]
- [SpringLine (for dogs & puppies – 23-44 lbs. and 8 weeks or older) – picture of dog in weight class]
- [SpringLine (for dogs & puppies – 45-88 lbs. and 8 weeks or older) – picture of dog in weight class]
- [SpringLine (for dogs & puppies – 89-132 lbs. and 8 weeks or older) – picture of dog in weight class]

[FOR DOGS & PUPPIES – Use only on dogs weighing up to 22 lbs. and 8 weeks or older]

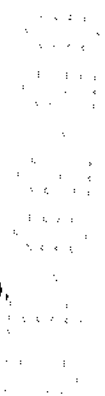
[FOR DOGS & PUPPIES – Use only on dogs weighing 23-44 lbs. and 8 weeks or older]

[FOR DOGS & PUPPIES – Use only on dogs weighing 45-88 lbs. and 8 weeks or older]

[FOR DOGS & PUPPIES – Use only on dogs weighing 89-132 lbs. and 8 weeks or older]

Optional Marketing Claims [Fleas, Ticks, Chewing Lice]

- [Fast-acting, long-lasting, convenient spot treatment for control of fleas, ticks and chewing lice]
- [Kills ticks that may transmit vector borne diseases]
- [Waterproof]
- [C712.0 FOR DOGS provides convenient and effective flea, tick, and chewing lice control for dogs and puppies.]
- [Fast acting and long-lasting]
- [Prevents re-infestation]
- [Convenient to use]
- [Kills (newly emerged) adult fleas before they lay eggs]
- [Controls fleas which may cause flea allergy dermatitis]
- [Kills all stages of brown dog ticks (*R. sanguineus*), American dog ticks (*D. variabilis*), lone star ticks (*Amblyomma americanum*), and deer ticks (*Ixodes scapularis*)(which may carry Lyme disease)]
- [Rapidly eliminates infestations with chewing lice]
- [Aids in control of sarcoptic mange infestations]



- [Can be used on breeding, pregnant and lactating bitches]
- [Waterproof (water resistant)]
- [Prevents infestation]
- [Kills fleas that may cause (flea allergy dermatitis) (and) (flea bite dermatitis)]
- [Protects for one month]
- [Effective monthly treatment of fleas, ticks and lice]
- [Remains effective after bathing and swimming]
- [Kills the vectors that may transmit; Lyme disease, Rocky Mountain spotted fever, babesiosis, ehrlichiosis, bartonellosis, hepatozoonosis]
- [(Easy,) (fast,)(effective) control of fleas, ticks and lice]
- [Kills fleas (ticks) (lice)]
- [Kills fleas that may cause anemia]
- [Optional graphics: Picture of Flea]
- [Optional graphics: Picture of tick]
- [Optional graphics: Picture of louse]
- [Contains the proven effective topical fipronil]
- [Contains the proven effective topical fipronil found in Frontline*]
- [Convenient to use]
- [Long lasting]
- [Fast acting]
- [Eliminates infestations with chewing lice]
- [Controls and prevents re-infestation]
- [Kills all stages of deer ticks]
- [Prevents infestations]
- [Apply monthly]
- [Controls mites that may cause sarcoptic mange]
- [Best results when used monthly (year round)]
- [For year round protection]
- [Kills newly emerged fleas before they lay eggs]
- [Calendar stickers inside]
- 3 Doses
- Controls flea re-infestation for up to one month (4 weeks)
- [Contains (Fipronil) the active ingredient used in Frontline Top Spot® for Dogs]
- [C712.0 FOR DOGS is not manufactured by or distributed by Merial Limited.]
- [Frontline Top Spot® is a registered trademark of Merial Limited.]
- [Contains Fipronil (the active ingredient used in Frontline Top Spot® for Dogs)]
- [Compare to Frontline Top Spot® for Dogs]
- [C712.0 FOR DOGS is not manufactured by or distributed by Merial. Frontline is a registered trademark of Merial]

EPA Reg. No. 88052-xxxx

EPA Est. 74720-DEU-01

ACTIVE INGREDIENT:

Fipronil 9.7%

INERT INGREDIENTS: 90.3%

TOTAL: 100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

See [back (side) panel and insert] for additional Precautionary and First Aid Statements

NET CONTENTS:

[Three (3) 0.023 fl. oz. (0.67 mL) (applicators) (pipettes)]

[Three (3) 0.045 fl. oz. (1.34 mL) (applicators) (pipettes)]

[Three (3) 0.091 fl. oz. (2.68 mL) (applicators) (pipettes)]

[Three (3) 0.136 fl. oz. (4.02 mL) (applicators) (pipettes)]

[CAT PROHIBITION ICON]

DO NOT USE ON CATS. Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian.

Side Effects. Monitor your dog after application. Side effects may include skin irritation such as redness, scratching or other signs of discomfort. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects occur, consult your veterinarian or us at xxx-xxx-xxxx.

[BACK PANEL OF CARTON – 3 x 0.023 FL. OZ. PACKAGE]

[BACK PANEL OF CARTON – 3 x 0.045 FL. OZ. PACKAGE]

[BACK PANEL OF CARTON – 3 x 0.091 FL. OZ. PACKAGE]

[BACK PANEL OF CARTON – 3 x 0.136 FL. OZ. PACKAGE]

C712.0 FOR DOGS 8 weeks or older

C712.0 FOR DOGS contains the active ingredient fipronil that effectively targets fleas, ticks, and chewing lice. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not allow children to apply product. To prevent injury to you and your dog, read entire label and directions on the package insert before each use. Follow all directions and precautionary statements carefully. This product must only be used on dogs. Do not use on rabbits or on other animals.

[Precaucion al consumidor: si usted no puede leer inglés, no use este producto hasta que la etiqueta le haya sido explicada ampliamente. (To the user: If you cannot speak English, do not use this product until the label has been fully explained to you).]

To kill fleas and all stages of brown dog ticks, American dog ticks, lone star ticks, and deer ticks (which may carry Lyme disease) and chewing lice, apply this product to dogs and puppies (8 weeks or older) as follows.

To remove and open (applicator) (pipette): See label insert for opening instructions.

INSTRUCTIONS FOR APPLYING PRODUCT

To apply C712.0 for Dogs: Place (applicator) (pipette) tip through dog's hair to the skin level between the shoulder blades. Squeeze (applicator) (pipette), applying entire contents in a single spot to the dog's skin. Avoid superficial application to the dog's hair. Allow area to dry before touching treated area. Only one (applicator) (pipette) per treatment is needed.

OR [Alternate application method]

For dogs & puppies weighting up to 22 lbs. Apply one (applicator) (pipette) from the back of the neck to a point midway between the neck and tail.

OR [Alternate application method]

For dogs & puppies weighting up to 22 lbs. Apply one (applicator) (pipette) starting at the base of the tail moving in a straight line toward head against the hair along the backbone (spine).

C712.0 for Dogs can also be used for the treatment and control of flea, tick, and chewing lice infestations on breeding, pregnant, and lactating bitches. C712.0 for Dogs aids in the control of sarcoptic mange infestations. Multiple monthly treatments are recommended for the elimination of mites.

FREQUENCY OF APPLICATION

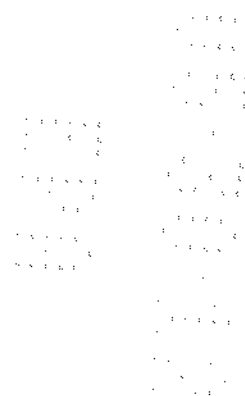
When used monthly, C712.0 for Dogs completely controls flea, tick, and chewing lice infestations. Research demonstrates that C712.0 for Dogs kills adult fleas up to three months. Although C712.0 for Dogs can control fleas for up to three months, if there is a high risk of re-infestation or if the dog has fleas which may cause flea allergy dermatitis, a once monthly application may be needed. C712.0 for Dogs kills ticks for at least one month. A once monthly application is recommended where tick control is needed. A once monthly application is recommended where chewing lice are present. C712.0 for Dogs remains effective even after bathing, water immersion, or exposure to sunlight. Do not reapply C712.0 for Dogs for 30 days.

Manufactured for:

Horizon Valley Generics, Inc.
1201 Walnut Street, Suite 2900
Kansas City, Missouri 64106

MADE IN Germany

C712.0 FOR DOGS/ trade name is a registered trademark of Horizon Valley Generics, Inc.
©2012 Horizon Valley Generics, Inc. All rights reserved.



[FRONT OF LABEL DIRECTIONS FOR PACKAGE INSERT –
3 x 0.023 FL. OZ. PACKAGE]
[FRONT OF LABEL DIRECTIONS FOR PACKAGE INSERT –
3 x 0.045 FL. OZ. PACKAGE]
[FRONT OF LABEL DIRECTIONS FOR PACKAGE INSERT –
3 x 0.091 FL. OZ. PACKAGE]
[FRONT OF LABEL DIRECTIONS FOR PACKAGE INSERT –
3 x 0.136 FL. OZ. PACKAGE]

C712.0 FOR DOGS 8 weeks or older

EPA Reg. No. 88052-xxxx

EPA Est. 74720-DEU-01

ACTIVE INGREDIENT:

Fipronil 9.7%

INERT INGREDIENTS: 90.3%

TOTAL: 100.0%

Kills fleas and all stages of brown dog ticks, American dog ticks, lone star ticks, and deer ticks (which may carry Lyme disease) and chewing lice

KEEP OUT OF REACH OF CHILDREN

CAUTION

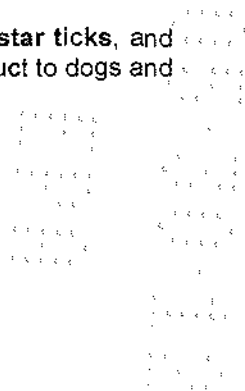
C712.0 for Dogs contains the active ingredient fipronil that effectively targets fleas, ticks, and chewing lice. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity.

DIRECTIONS FOR USE

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Precaucion al consumidor: si usted no puede leer inglés, no use este producto hasta que la etiqueta le haya sido explicada ampliamente. (To the user: If you cannot speak English, do not use this product until the label has been fully explained to you).

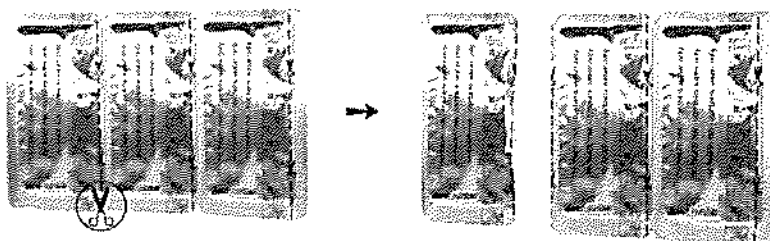
To kill fleas and all stages of brown dog ticks, American dog ticks, lone star ticks, and deer ticks (which may carry Lyme disease) and chewing lice, apply this product to dogs and puppies (8 weeks or older) as follows.



To remove and open (applicator) (pipette):

[ILLUSTRATIONS FOR OPENING PRODUCT]

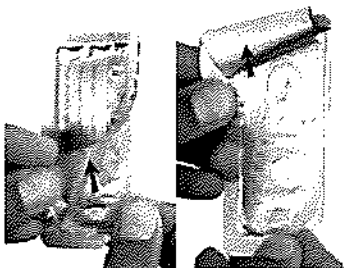
- ❶ Cut along scissor cut line to separate unit



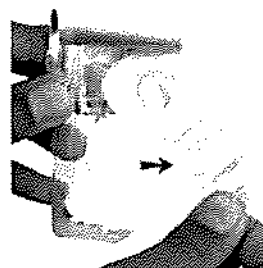
- ❷ Turn unit over and cut corner at bulb end



- ❸ From cut corner, peel backing completely off from bottom to top



- ❹ Remove the applicator



[ILLUSTRATIONS FOR APPLYING PRODUCT]

To apply C712.0 for Dogs: Place (applicator) (pipette) tip through dog's hair to the skin level between the shoulder blades. Squeeze (applicator) (pipette), applying entire contents in a single spot to the dog's skin. Avoid superficial application to the dog's hair. Allow area to dry before touching treated area. Only one (applicator) (pipette) per treatment is needed.

OR [Alternate application method]

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OR [Alternate application method]

For dogs & puppies weighting up to 22 lbs. Apply one (applicator) (pipette) starting at the base of the tail moving in a straight line toward head against the hair along the backbone (spine).

C712.0 for Dogs can also be used for the treatment and control of flea, tick, and chewing lice infestations on breeding, pregnant, and lactating bitches. C712.0 for Dogs aids in the control of sarcoptic mange infestations. Multiple monthly treatments are recommended for the elimination of mites.

FREQUENCY OF APPLICATION

When used monthly, C712.0 FOR DOGS completely controls flea, tick, and chewing lice infestations. Research demonstrates that C712.0 FOR DOGS kills adult fleas up to three

months. Although C712.0 FOR DOGS can control fleas for up to three months, if there is a high risk of re-infestation or if the pet has fleas which may cause flea allergy dermatitis, a once monthly application may be needed. C712.0 FOR DOGS kills ticks for at least one month. A once monthly application is recommended where tick control is needed. A once monthly application is recommended where chewing lice are present. C712.0 FOR DOGS remains effective even after bathing, water immersion, or exposure to sunlight. Avoid contact with treated area until dry. Do not reapply C712.0 FOR DOGS for 30 days.

[CAT PROHIBITION ICON]

DO NOT USE ON CATS. Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian.

Side Effects. Monitor your dog after application. Side effects may include skin irritation such as redness, scratching or other signs of discomfort. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects occur, consult your veterinarian or us at xxx-xxx-xxxx.

[BACK OF LABEL DIRECTIONS FOR PACKAGE INSERT –
3 x 0.023 FL. OZ. PACKAGE]

[BACK OF LABEL DIRECTIONS FOR PACKAGE INSERT –
3 x 0.045 FL. OZ. PACKAGE]

[BACK OF LABEL DIRECTIONS FOR PACKAGE INSERT –
3 x 0.091 FL. OZ. PACKAGE]

[BACK OF LABEL DIRECTIONS FOR PACKAGE INSERT –
3 x 0.136 FL. OZ. PACKAGE]

C712.0 FOR DOGS

FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation persists.

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes.

Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice.

Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

HOTLINE NUMBER: Have the product container or label with you when calling a poison control center, doctor or going for treatment. You may contact us at xxx-xxx-xxxx for emergency medical treatment information.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS

CAUTION. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

HAZARDS TO DOMESTIC ANIMALS

For external use only. Do not use on puppies under 8 weeks of age. Individual sensitivities, while rare, may occur after using any pesticide product. Dogs may experience some temporary irritation at the site of product application. If signs persist, or become more severe within a few days of application, consult a veterinarian. If your dog has an unusual reaction to the initial application, consult a veterinarian before repeating treatment. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated or aged dogs. Call 1-xxx-xxx-xxxx for 24-hour assistance.

QUESTIONS OR COMMENTS ABOUT THIS PRODUCT

Call xxx-xxx-xxxx

[GRAPHICS/PICTURES]

[PRODUCT BAR CODE]

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage. Store unused product in original container only, out of reach of children and animals.

PESTICIDE DISPOSAL. If partly filled, call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

CONTAINER DISPOSAL. If empty: Non refillable container. Do not reuse this container. If empty: Place in trash or offer for recycling if available.

HOW SUPPLIED

C712.0 FOR DOGS is available in convenient sizes for small dogs and puppies 8 weeks or older and up to 22 lbs., medium dogs 23-44 lbs., large dogs 45-88 lbs., and extra-large dogs 89-132 lbs.

up to 22 lbs.	Contains 3 - 0.023 fl. oz. (0.67 mL) (applicators) (pipettes)
23-44 lbs.	Contains 3 - 0.045 fl. oz. (1.34 mL) (applicators) (pipettes)
45-88 lbs.	Contains 3 - 0.091 fl. oz. (2.68 mL) (applicators) (pipettes)
89-132 lbs.	Contains 3 - 0.136 fl. oz. (4.02 mL) (applicators) (pipettes)

WARRANTY

To the extent consistent with applicable law, Horizon Valley Generics, Inc. and/or seller makes no warranty, expressed or implied, concerning the use of this product other than indicated on the label. Buyer assumes all risk of use resulting from the handling of this product. Seller shall return the purchase price or at the election of the seller replace the product.

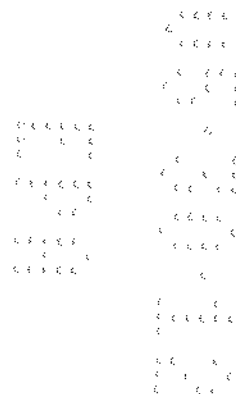
Manufactured for:

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MADE IN Germany

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[Pictogram of Front of Blister With Opening Instructions – NOT PART OF LABEL]



[Pictogram of Back of Blister With Opening Instructions – NOT PART OF LABEL]



[Text for Back of Blister Pack]

Keep Out of Reach of Children

See full label for additional instructions

CAUTION

Only for Dogs & Puppies

C712.0 for Dogs

EPA Reg. No. 88052-xxxx

Lot No.

[0.023 fl. oz.]

[0.045 fl. oz.]

[0.091 fl. oz.]

[0.136 fl. oz.]

